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Aspects of a Changing Structure

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Abstract

In 1988, the Environmental Protection Agency administratively adopted a negligible risk or *de minimis* standard for registering pesticide uses in agriculture. The *de minimis* standard provides opportunity to lower the carcinogenic risk from pesticide residues in food. By providing a market for negligible risk pesticides, the new standard will likely allow reduction in use of the more hazardous compounds. Further, the new standard could lower food production costs if fewer uses of currently registered pesticides are banned. However, the agency's lack of data and safety margin procedures can potentially result in underestimates or overestimates of tumor risk. This report is based on papers and discussions at a Southern Agricultural Economics Association symposium in New Orleans in 1988.

Keywords: pesticide, registration, Delaney Clause, Environmental Protection Agency

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Contents

Page

Highlights iii

Introduction 1

Regulation of Pesticides in Food: Addressing the Delaney
Paradox Policy Statement, by Deborah Sisco 5

Welfare Implications of EPA's New Registration Standard:
The Case of Fresh Market Tomatoes, by Walter L. Ferguson 17

Risk Assessment and Regulatory Priorities for Pesticide
Residues in Food, by Gerald A. Carlson 32

Summary 40

Highlights

In 1988, the Environmental Protection Agency (EPA) changed its standards for applying the Delaney Clause of the Federal Food, Drug, and Cosmetic Act (FFDCA). EPA changed from a zero carcinogenic risk to a negligible risk or *de minimis* standard when deciding whether or not to issue tolerances for residues of pesticide products on foods. A residue tolerance is necessary before a pesticide can be registered for use on a food crop. The Delaney Clause prohibits the approval of an additive to food that has been found to induce cancer in either humans or animals, or under EPA's interpretation, to induce either benign or malignant tumors. For pesticides, the Delaney Clause applies only to those pesticides that concentrate in processed foods.

The old zero risk standard prohibited the approval of a tolerance for pesticide residues found to induce cancer in humans or in animals when the residues of that pesticide concentrate in processed food or feed above the level allowed in the raw agricultural commodity. The *de minimis* standard, as currently interpreted, allows all pesticide tolerances on a crop to be revoked when the combined oncogenic risk of benign or malignant tumors from the residues on processed forms of a crop exceeds 1×10^{-6} or one of 1 million persons who are potential consumers of the crop over a lifespan of 70 years.

The *de minimis* standard allows a more consistent approach in granting tolerances for residues of pesticides on food than the zero risk policy, because a uniform set of criteria is used for the raw or processed forms of the food. Under the old standard, when residues were found to concentrate in the processed portion of a crop, tolerances would be denied on an entire crop, even though benefits might justify risks of the pesticide uses on the raw forms of the foods. Under the new policy, EPA will issue a tolerance on both the raw and processed forms of a food when the residues of the pesticides on the food pose at most a negligible risk of cancer.

The *de minimis* standard provides opportunity to lower the carcinogenic risk from pesticide residues in food. By facilitating the registration of new, negligible risk pesticides, the new standard could allow reduction in use of previously registered, more hazardous compounds. Further, the new standard could lower food production costs if fewer uses of currently registered pesticides are banned. The increase in new registered pesticide uses also could reduce the adverse economic effects of banning the more hazardous compounds.

Pesticide bans are generally predicted to cause net losses in economic efficiency and a redistribution of income from consumers to growers, with windfall revenue gains to nonuser growers, and gains or losses in revenue to user growers, depending on the crop's price elasticities of demand, and the supply and cost of alternative control.

Compared with pesticide bans of all registered uses, the use of tolerances as maximum legal limits to which farmers, processors, and others adjust may be a more efficient procedure. Farmers can lower dosages used, limit late season use, or switch methods of application to prevent crop produce from being found above tolerances and confiscated or rejected by private or public inspectors.

Some important economic and pest management reasons for retaining use rather than banning older compounds include the avoidance of target pest resistance that is associated with a reduced pesticide selection, the generally lower crop production costs in contrast with newer compounds, and the existing knowledge of farmers and other users concerning proper storage, handling, and application of the pesticides in current use.

Caution by EPA is needed in its use of current risk assessment procedures in evaluating registration of pesticide uses. The agency's lack of data and its safety margin procedures can potentially cause

errors in the estimates of tumor risk. Components of risk assessment that are subject to error include pesticide use levels, pesticide residue concentrations, human consumption of pesticide residues, and potency of pesticides.

Pesticide Residues and Food Safety

Aspects of a Changing Structure

Introduction

In the midst of the concern over food safety and questions about chemical residues in the food supply, the Environmental Protection Agency (EPA) has changed the method by which it will consider granting registrations to new, or new uses to old pesticide products. In striving to provide a more consistent approach in the manner in which pesticide products are registered for sale and use, the EPA has attempted to reconcile the often conflicting stipulations of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) with the Delaney Clause portion of the Federal Food, Drug, and Cosmetic Act (FFDCA).

FIFRA and FFDCA authorize the EPA to regulate pesticide uses and their residues in food and feed. FIFRA empowers EPA to: (1) register pesticide products prior to their being marketed, specifying the terms and conditions of their use and (2) remove unreasonably hazardous pesticides from the market. Under the FFDCA, the EPA establishes tolerance levels defining the maximum levels of pesticide residues that may be legally present in foods and animal feed sold in interstate commerce.

Under FIFRA, EPA registration of the use of pesticide products occurs only after the determination is made that no unreasonable adverse effects on man or the environment will take place. That is, FIFRA stipulates taking into account the economic, social, and environmental costs and benefits of pesticide use. Registrations license specified uses of a pesticide product, using specific terms and conditions for the use of the product. The terms and conditions of use must be specified on container or package labels, which may include precautionary statements, restriction of pesticide use to trained applicators, and field re-entry intervals. Other conditions of registration may require modification of product use or formulations, and packaging limitations.

To register a pesticide use, pesticide manufacturers must provide the EPA with information describing the acute and chronic effects of human exposure and toxicity, as well as environmental fate studies. Exposure information is data about the extent to which people are exposed to the pesticide product residues in the air, water, and food. Toxicity information is data on the health effects of a given level of exposure. An assessment of the level of risk associated with a particular pesticide is the combined effects of exposure and toxicity.

A paradoxical situation occurs when a pesticide product, which is considered a food additive for purposes of the FFDCA, is a known carcinogen and is present on individual food commodities at levels that would expose the general population to an expected risk level greater than one additional case of cancer for every 1 million individuals (1×10^{-6}) over a lifetime of exposure (70 years). The key issue for registering a carcinogenic compound under FIFRA is weighing the risks to consumers in a product's food uses as well as exposure of farmworkers and pesticide applicators against the economic benefits derived. Under the FFDCA's Delaney Clause however, residues of a known carcinogenic compound that will concentrate in a processed food cannot be granted a tolerance. That is, the FFDCA sets forth a strictly risk-based criterion when considering tolerances for food additives.

If a particular tolerance cannot win FFDCA approval, then no registration can be granted for use of the chemical on that food under FIFRA regardless of the possible benefits that particular use of the chemical would confer.

In 1985, the National Academy of Sciences (NAS) received an EPA grant to study EPA's methods for setting pesticide tolerance levels. The mission was to examine the current and likely effects of the Delaney Clause on the tolerance-setting process.

The EPA's tolerance-setting process establishes tolerances for pesticide residues on raw commodities under section 408 of the FFDCA, which states that tolerances are to be set at levels deemed necessary to protect public health, while allowing for the ability to provide an adequate, wholesome, and economical food supply. Section 408, thus, implicitly recognizes that pesticide uses confer both benefits and risks to consumers, and that both should be weighed when setting raw commodity levels.

Section 409 of the FFDCA governs pesticide residues in processed foods. Such residues must be proven safe for human consumption; the consideration of a pesticide's benefits to consumers is not authorized. Section 409 also contains the Delaney Clause, which prohibits the approval of a tolerance for a food additive found to induce cancer in humans or in animals, generally referred to as the "zero-risk standard." Section 409, therefore, bars the EPA from granting any tolerance for a pesticide residue that has been found to induce cancer in animals and that concentrates in processed food.

Here then is the paradox: a new pesticide whose residues in food pose a relatively low risk of cancer may be barred from registration because of Delaney Clause constraints, while residues of an old pesticide that pose a higher risk and that is used for the same purposes might remain on the market. Under the zero-risk standard, a pesticide use registered on the basis of a risk/benefit standard for agricultural use becomes subject to the Delaney Clause's zero-risk standard if the residues of the pesticide concentrate in processed food. If any portion of a crop to which an oncogenic pesticide has been applied is processed so that pesticide residues are concentrated, the EPA's policy is to deny both Section 409 and 408 tolerances for the pesticide's residues in that crop. If Section 408 tolerances cannot be granted for a pesticide residue in a given food, then EPA must also deny registration of the use of that pesticide in that crop/food under FIFRA.

The 1978 amendments to FIFRA directed EPA to reevaluate the registrations of the 600 active ingredients used in 50,000 pesticide products with better data documenting carcinogenicity and other risks provided by the pesticide manufacturers. The EPA's policy concerning the application of the Delaney Clause for new products is clear. If an oncogenic pesticide concentrates in processed food, neither Section 409 nor 408 tolerances can be granted, and the product cannot be issued a registration. However, the EPA must determine how to apply the zero-risk standard of the Delaney Clause to the large number of currently registered and commercially important pesticide products. An important problem discussed in the NAS study is that sequential tolerance revocations or denials for one active ingredient at a time could have in some cases actually increased human dietary oncogenic risk by increasing the use of a more hazardous compound after tolerances for a less toxic compound were revoked.

The EPA's policies toward the uses of older pesticides may likely change as technology continues to become increasingly sophisticated in detecting pesticide residues in processed food. The question of whether any residues in food of possible human carcinogenic pesticides are acceptable becomes more compelling as does the issue of what level of determined risk will ensure sufficient food and the economic viability of the agricultural sector.

The NAS evaluated 28 oncogenic compounds and determined that:

- 55 percent of total dietary oncogenic risk derives from residues on crops that are consumed in both the raw and processed form, with 35 percent of dietary risk linked to consumption of the raw form, and the remaining 20 percent from consumption of the processed form; and

- 45 percent of dietary oncogenic risk stems from foods EPA considers to have no processed form, including many fruits, vegetables, and poultry products.

The NAS study indicates that strict application of the Delaney Clause would eliminate only about 20 percent of the estimated dietary oncogenic risk from consumption of pesticide residues in processed food only. Another 35 percent of the risk would be eliminated from consumption of raw forms of the processed foods since EPA denies section 408 tolerances when section 409 tolerances cannot be established. However, the foods accounting for nearly half of the total estimated dietary risk are beyond the scope of the Delaney Clause, because under current EPA guidelines these foods have no processed form.

The NAS study analyzed two zero-risk standard scenarios and two negligible-risk standard scenarios to regulate oncogenic residues:

Scenario 1

A zero-risk standard is applied for oncogenic risk to all pesticide residues in foods which are processed (concentrating residues) only, that is the previous interpretation of the Delaney Clause. When residues of an oncogenic pesticide are present in the processed portion of a crop, both raw and processed tolerances are revoked. In this scenario, the revoked tolerances reduce dietary risk (from the 28 pesticides) by 55 percent but this standard ignores about 45 percent of total estimated dietary risk from foods with no processed form.

Scenario 2

A negligible-risk standard is applied that requires all pesticide tolerances on a crop be revoked when the combined oncogenic risk from the residues of that pesticide on both the raw and processed forms of a crop exceeds 1×10^{-6} or 1 in 1 million. This negligible-risk standard reduces the total estimated risk from the 28 compounds by 98 percent, while revoking 32 percent of the tolerances.

Scenario 3

A zero-risk standard is applied for oncogenic risk to all pesticide residues on both raw and processed foods. If the EPA determines a pesticide is oncogenic, all food tolerances for the pesticide are revoked. The revocation of all tolerances for all oncogenic pesticides results in the elimination of all dietary oncogenic risk.

Scenario 4

Pesticide tolerances on a crop are revoked when the total risk from residues of a pesticide on all processed forms of a crop exceeds 1×10^{-6}. Here, both raw and processed food tolerances are revoked. This negligible-risk standard eliminates only 35 percent of estimated dietary oncogenic risk, while revoking the smallest percentage of all tolerances.

Thus, of the four alternative scenarios, the negligible-risk standard applicable to residues on both raw and processed food (scenario 2) was determined to offer the highest percentage of benefits. Further,

these results suggest that progress toward risk reduction could be greatest and most uniform when raw and processed foods are subject to a consistent risk standard, while allowing for the ability to provide an adequate, wholesome, and economical food supply.

Based on the NAS recommendations, EPA has recently adopted a *de minimis* approach to the situation, which essentially abrogates the Delaney Clause stipulations.

However, the issue of pesticide residues in the food supply and acceptable levels of exposure remains the object of efforts to amend the FIFRA and FFDCA in Congress. There have been suggestions for defining alternative risk levels including 1×10^{-5}, or one extra cancer case per 100,000 individuals over a lifetime of exposure, increasing the hypothetical cancer incidence by a factor of 10. Some in EPA have stressed that the agency requires this type of flexibility in its pesticide regulatory decisions to ensure that effective pest control methods remain available to agriculture. In addition, the USDA has proposed for fiscal 1991 a Food Safety Data Initiative that would provide funding for the collection and analysis of data describing pesticide use, residue levels, and potential exposure levels from selected commodities in the Nation's food supply. Information with which to make regulatory decisions would be substantially improved.

In the interim, lacking any change in the governing Federal codes or improvement in the information base describing the present food residue and exposure situation, EPA must make regulatory decisions based on current interpretation of the law.

This report explores the Delaney Clause paradox and the EPA's rationale for altering the method by which pesticides are evaluated. The methodology by which the NAS arrived at its recommendations to the EPA is reviewed, and an example of the economic effects of alternative levels of acceptable risk for food tolerances is provided. Deborah Sisco (EPA/Office of Pesticide Programs) describes the EPA's position prior to delivery of the NAS recommendations and the policy that the agency has adopted in response to those recommendations; that is, apply a negligible-risk approach whenever possible in considering registration potential for new and existing pesticide products. Walter L. Ferguson (USDA/ERS) provides an economic assessment of the implications of EPA's switching from a zero-risk to a negligible-risk, or *de minimis* standard for a specific crop (tomatoes) and estimates the economic effect on producers and consumers under differing policy options. Gerald A. Carlson (North Carolina State University), a member of the committee that developed the response to EPA's original charge, analyzes the statutory framework for setting tolerances for pesticide residues in food, and explains the possibilities of over or underestimation of actual dietary risk based on the assumptions made by the NAS committee.

Regulation of Pesticides in Food

Addressing the Delaney Paradox Policy Statement

Deborah Sisco

The Environmental Protection Agency has long wrestled with the complexities and inconsistencies of the statutory mandates governing the regulation of pesticides whose use results in the presence of residues in food. The 1987 release of the National Academy of Sciences report on pesticides in food offered some recommendations to alleviate the then inconsistencies in statutory mandates involving the registration of pesticide uses. EPA responded with a statement announcing a new policy direction for the Agency in regulating potentially carcinogenic pesticides intended for use on food crops (Federal Register, Oct. 1988).

Deborah Sisco, a primary author of EPA's 1988 policy statement, provides an abridged version of the statement with incorporated analysis supporting the Agency's new negligible-risk standard for registration of pesticide uses on food crops.

The Environmental Protection Agency (EPA) is responsible for regulating the sale and use of pesticide products under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The EPA also regulates pesticide residues on food under sections 408 and 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA). Food is "adulterated" and subject to seizure under the FFDCA if it is found to bear pesticide residues that are not permitted by appropriate section 408 and 409 tolerances. EPA interprets section 409 to allow the agency to consider benefits to food consumers in reaching its decisions unless the Delaney Clause applies. However, the Delaney Clause of section 409, if read literally, is a risk-only standard that bars the establishment of any food additive regulation that would authorize residues in or on processed food or feed of any pesticide that has been found to induce cancer when ingested by man or test animals with certain limited exceptions.

The difference in the standards of these two statutes presents EPA with a major problem in regulating certain pesticide chemicals that have been found to induce cancer in test animals. Such pesticides may be ineligible for food additive regulations under the FFDCA even if they have been found to pose no unreasonable risk to humans and qualify for registration under FIFRA. This problem may arise in three situations: (1) when a food additive regulation is sought for a new pesticide chemical (or a new use of a currently registered chemical) that induces cancer in animals, (2) when new residue data indicate a need for a food additive regulation for a registered pesticide known to induce cancer in animals, or (3) when new toxicity data show that a registered pesticide for which food additive regulations have been established induces cancer in animals.

In the first situation, the issue is whether to allow the pesticide to be marketed for a particular food use. EPA's current regulations prohibit FIFRA registration until the issuance of any needed tolerances and food additive regulations associated with the pesticide's use. The second and third situations require EPA to decide whether to make unlawful the marketing of a pesticide for those previously approved food uses subject to section 409. The number of uses in these latter two

categories is increasing as EPA receives more and more toxicity and residue data. Of significant concern are the differences in the standards now applied to old and new pesticides. Under current EPA practice, a new pesticide whose residues in food pose a relatively low risk of cancer may be barred from registration because of Delaney Clause constraints, while residues of an old pesticide that pose a higher risk and that is used for the same purposes might remain on the market.

To address these issues, in February 1985, the EPA commissioned the Board on Agriculture of the National Research Council/National Academy of Sciences (NAS) to examine the impact of the Delaney Clause on the tolerance-setting process and on EPA decisionmaking. The NAS committee formed to conduct this study included experts in agricultural pest control, pesticide development, agricultural economics, cancer-risk assessment, public health, food science, regulatory decisionmaking, and law.

The EPA has evaluated the recommendations of the NAS and has reached conclusions about a policy that would be based on those recommendations. In summary, under this policy, the EPA would apply a uniform set of criteria to all FIFRA registration decisions and all FFDCA section 408 tolerance and section 409 food additive regulation decisions. If the residues of a pesticide on a particular food would pose no risk or only a negligible risk, the pesticide's use on that food would be approved under both acts without any particular scrutiny of benefits (provided they meet the other requirements of FIFRA and the FFDCA). This has been EPA's practice with respect to decisions on pesticide residues that pose only noncancer risks, and with respect to decisions under FIFRA and under FFDCA section 408 on pesticide residues that may pose cancer risks. However, the new policy involving section 409 is a significant change from the old 409 policy. In the past, EPA has refused to issue a 409 and, therefore, a 408 tolerance if any cancer risk was present, thereby making registration of the pesticide use impossible under FIFRA.

Essentially, the same stipulations that currently exist would hold for those pesticides deemed to pose a greater than negligible risk not requiring a 409 clearance. A risk/benefit evaluation would determine the appropriateness of FIFRA registration and FFDCA clearances under sections 408 and 409. For chemicals requiring a 409 clearance, if the cancer risk for the pesticide use is greater than negligible, then no 409 tolerance can be issued because of Delaney, and, therefore, no 408 tolerance or FIFRA registration will be granted.

In summary, in the case of a pesticide residue in a food that requires a section 409 clearance and that poses a cancer risk that is greater than negligible, the Delaney Clause ordinarily bars approval of a tolerance. The EPA is unaware of any legal theory that would justify a change in its current practice of refusing to issue new food additive regulations in such situations (with certain exceptions). However, for pesticide residues on a food that pose at most a negligible risk of cancer and whose use requires section 409 clearances, EPA will change its current approach to the extent that, in the future, EPA intends to propose to issue food additive regulations on the basis of the *de minimis* doctrine.

Legal and Regulatory Background

EPA often must apply four different and sometimes conflicting statutory standards in deciding whether a particular tolerance should be set for a pesticide residue detectable in food: one under the FIFRA and three under the FFDCA.

<u>The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)</u>

The sale, distribution, and use of pesticides in the United States are governed directly by the FIFRA and are also influenced heavily by the FFDCA. FIFRA requires that all pesticides sold or distributed in the United States be registered in accordance with the statutory standard for registration set forth in

FIFRA. That standard requires, among other things, that the pesticide perform its intended function without causing "unreasonable adverse effects on the environment" (FIFRA section 3(c)(5)). The term "unreasonable adverse effects on the environment" is defined as "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide" (FIFRA section 2(b). Under FIFRA section 6, EPA may cancel the registration for a use of a pesticide (or require modifications in the terms and conditions of registration in lieu of cancellation) if the EPA determines that the risks of using the pesticide outweigh the benefits of the use.

It has been EPA's belief that pesticide users and food processors should be able to assume that a pesticide registered under FIFRA has the appropriate clearances under the FFDCA for the food uses listed on the FIFRA label, and, therefore, not to risk seizure of crops as adulterated.

Sections 408 and 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA)

Under FFDCA section 402, a raw agricultural commodity is adulterated if it contains a pesticide residue not authorized by a FFDCA section 408 tolerance (maximum permissible level) or an exemption from the requirement of a tolerance. An adulterated commodity sold or distributed in interstate commerce is subject to seizure by the Food and Drug Administration (FDA).

To establish a tolerance or exemption from tolerance under section 408, the EPA must find that the regulation would "protect the public health" (FFDCA section 408(b)). In reaching this determination, the EPA is directed to consider, among "other relevant factors," the necessity for the production of an adequate, wholesome, and economical food supply, and the other ways in which the consumer may be affected by the pesticide.

Under FFDCA section 402, processed food is adulterated (and hence subject to seizure) if it contains any food additive (including any pesticide residue) not authorized by a section 409 food additive regulation. An important exception to this provision is that a processed food containing pesticide residues resulting from the "carryover" from treatment at the raw agricultural commodity stage is not regarded as adulterated if the residue level in such a food is no greater than that allowed by the section 408 tolerance established for the raw agricultural commodity.

In EPA's view, the determination of whether use of a pesticidal food additive is "not harmful" or is "safe" should take into account the net effects of use of the pesticide on the food supply, including the benefit of an adequate, wholesome, and economical supply of food, as well as consideration of any potential harm to humans, wildlife, and the environment that may result from the pesticide's use. At least for residues of pesticide chemicals, EPA believes that this kind of benefit should be regarded as one of the "relevant factors" EPA may consider under FFDCA section 409(c)(5), even though it is not listed specifically in 409(c)(5) as it is in section 408(b). In contrast, FDA has tended to interpret the section 409 general safety clause as a criterion that focuses solely on the risks to the food supply caused by the food additive, as opposed to the risks avoided, and this view has considerable support in the legislative history of section 409 and in scholarly journals.

The Delaney Clause

The one clear exception to the EPA's latitude to balance risks and benefits for food additives under section 409 is the "Delaney Clause" in section 409(c)(3). The Delaney Clause states that residue of a food additive shall not be deemed safe "if it is found to induce cancer when ingested by man or animal or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal." Because FFDCA section 408 contains no counterpart

to the Delaney Clause, the EPA has the authority to evaluate the risk posed by the presence of residues of a carcinogenic pesticide in a raw agricultural commodity, and to establish a section 408 tolerance at a level which will protect the public health, taking benefits to consumers of an economical food supply into account. As long as the processed food will not contain residues above the level allowed in the raw agricultural commodity, residues of that carcinogenic pesticide may legally be present in such processed food. However, where residues of the chemical concentrate to a level above the section 408 tolerance level during processing, or result from use of a pesticide during or after processing, a food additive regulation might be prohibited by the Delaney Clause.

The Delaney Clause has long been regarded as allowing the administering EPA to exercise scientific judgment and discretion in deciding whether a food additive "induces cancer" in animals. EPA has generally assumed that, for purposes of the Delaney Clause, a substance "induces cancer" in animals if, in a well-conducted animal feeding study, a statistically significant increase in the incidence of histologically related tumors (benign, malignant, or combined) is observed in treated animals compared with concurrent control animals, unless there is a reason to conclude that the observed increase is unrelated to the ingestion of the test substance. Under this approach, a pesticide may be found to "induce cancer" in animals despite the fact that increased tumor incidence occurs only at high doses, or that only benign tumors occur, and despite negative results in other animal feeding studies. FDA has taken a similar approach in assessing data for the purposes of the Delaney Clause.

There is at least "limited evidence" of carcinogenicity (virtually all from animal studies) for 66 or more of the approximately 350 food-use pesticides already approved for use under the classification scheme set forth in EPA's "Guidelines for Carcinogen Risk Assessment." EPA expects this number to become somewhat larger as it receives and evaluates more studies on the food-use pesticides. A substantial number of these pesticides require section 409 food additive regulations for one or more of their uses.

Current Policy Has Been Constrained by the Delaney Clause

From the foregoing discussion, it is apparent that if EPA determines that residues of a pesticide in food pose a cancer risk that is greater than negligible and that outweighs the pesticide's benefits to consumers, the pesticide's FIFRA registration should be cancelled for at least some food uses, and its FFDCA section 408 and 409 clearances should be revoked. There is no conflict between the various standards in such a case, and EPA's current practice reflects this lack of conflict.

Difficulties arise in the two remaining situations. Residues of a pesticide may pose only a negligible cancer risk, or residues may pose a cancer risk that is greater than negligible but nonetheless is not so great as to outweigh the pesticide's benefits to consumers of a wholesome and economical food supply. In both of the latter situations, EPA views FIFRA and FFDCA section 408 as allowing the registration or continued registration of the pesticide and the issuance or continuation of needed FFDCA clearances. But the Delaney Clause of FFDCA section 409 arguably bars the issuance of new section 409 clearances for pesticides in either of the latter two situations, and thus concomitantly calls into question the status of such pesticides under FFDCA section 408 and FIFRA.

Due to the constraints dictated by the literal approach to the Delaney Clause, the EPA has not been willing to register a carcinogenic pesticide for a new food use that requires a section 409 food additive regulation, even though that pesticide meets the risk/benefit standards in the other statutory provisions. Because there is often no practical way to assure that the raw agricultural commodity at issue will not be processed, the EPA generally does not grant a section 408 tolerance for residues of the pesticide on a raw agricultural commodity in a situation where an associated section 409 food additive regulation is needed but cannot be issued.

If the pesticide use (not subject to section 409) passes the risk/benefit test under FIFRA and FFDCA section 408, a registration can be granted. This is true even if the estimated dietary cancer risk to the public is the same as or higher than the risk posed by an analogous pesticide use for which a food additive regulation is required. Thus, very similar risk situations have been treated quite differently because of the inconsistent statutory provisions. This approach has not necessarily resulted in lower health risks for the public. In fact, there is a strong argument that in some cases the constraints of the Delaney Clause paradoxically may have led to greater risks to the public. New pesticides that pose lower cancer risks than pesticides currently on the market have been denied registration, while older, more hazardous pesticides remained in use.

To date, the EPA has not taken action based on the Delaney Clause to revoke established food additive regulations. In many instances, taking such action would require EPA either to revoke the associated 408 tolerances and cancel the FIFRA registration (despite the risk/benefit criteria that would govern such actions), or to abandon its longstanding policy that the lawful application of a pesticide should not result in illegal pesticide residues. Many of the residues of these pesticides appear to pose low or negligible risks and the pesticides themselves have substantial benefits for the production of food in this country. The EPA has deferred action in such cases, while studying the dilemma posed by the statutory scheme.

It should be noted that a registrant of a pesticide use faced with a proposed FIFRA cancellation based entirely or primarily on the fact that the pesticide's residues are not thought to be "safe" within the meaning of FFDCA section 409 might assert that a FIFRA cancellation cannot be based on criteria imported from the FFDCA, and might succeed in court (see *Continental Chemists Corp. v. Ruckelshaus*, (1972)).

The system that has been used by EPA so far has the added undesirable feature of placing new pesticides that are barred from registration because of the strict reading of the Delaney Clause at a disadvantage relative to old products that are shown by new data to pose comparable or higher risks. Given the high costs of data development, there is little incentive to develop a new food use pesticide that shows carcinogenic potential--even if the risk it would pose would be minimal, and even if it could replace an old product that poses a higher risk--if initial registration is likely to be barred by the Delaney Clause. Thus, the development of new, lower risk chemicals to replace old, higher risk pesticides may have been retarded by the EPA's past implementation of the Delaney Clause.

A reassessment of the data in support of the tolerances for a particular pesticide chemical may present another serious concern. The data review by the EPA may reveal, with respect to a chemical that induces cancer in animal studies, that not all the necessary section 409 tolerances are in place. New residue data or a new review of old data may lead the EPA to determine that residues concentrate during processing, and section 409 food additive regulations have not been promulgated to cover this situation. If the EPA cannot promulgate such regulations because of the Delaney Clause ban, these processed commodities may contain illegal residues that would make them subject to seizure by FDA. To prevent the presence of these residues in the processed commodities, the EPA would have to cancel the corresponding FIFRA registrations and revoke FFDCA section 408 tolerances (unless appropriate use restrictions on the pesticide labeling could be developed to prevent the use of the pesticide on commodities destined for processing). Such action could profoundly limit the legal use of many pesticide chemicals.

The EPA is facing the issues discussed here with an ever-increasing number of old pesticide chemicals. EPA's decision on whether to attempt to apply the section 409(c) criteria retrospectively under section 409(h) may depend on whether its approach to negligible-risk situations, set forth in this paper, is upheld.

Potential for Legislative Solution

The administrative approaches discussed so far in this paper would solve only some of the problems the EPA faces in this area. Moreover, implementing those approaches will be controversial and might involve the EPA in protracted litigation that could cause uncertainty and make it difficult for businesses to make plans about pesticide development and pesticide use. A legislative solution, stating clearly that the EPA has the authority to grant food additive regulations for pesticide residues posing at most a negligible risk, clearly would be desirable. Additional legislative changes would be required to allow the EPA to fully reconcile FFDCA and FIFRA. Such legislation ideally would give EPA the latitude to establish tolerances and food additive regulations for pesticides under a risk/benefit standard compatible with FIFRA, with a definitive statement that clearances for both raw and processed foods are to be established under a risk/benefit approach.

Response to NAS Recommendation for Consistency

The EPA agrees completely with the NAS report's most important conclusion that a consistent approach ideally should be followed in the regulation of pesticides for food uses, regardless of whether the pesticides are new or old or whether the foods are raw or processed. As the NAS report points out, there is no scientific reason to regulate pesticide residues in raw commodities differently from those in processed commodities. For risk assessment purposes, what is critical is not the type of food or feed commodity on which residues are present, but rather the identity and magnitude of the residues in the food and the associated consumption pattern. Likewise, EPA agrees with NAS that pesticides should be regulated consistently whether they are newly developed or have been on the market for many years.

Use of regulatory criteria that reflect this recommendation would allow the EPA to regulate high-risk pesticides more stringently than those that pose low risks, and permit the registration of new pesticides that offer substantial benefits and pose relatively insignificant risks. Riskier pesticides could then be replaced, and the total dietary risk reduced, with only minor adverse effects on food production.

The EPA believes that the most desirable way to achieve consistency in regulating potentially carcinogenic food-use pesticides would be to evaluate them under the same risk/benefit standard for 408 tolerance purposes. Table 1 outlines the regulatory outcomes that EPA would favor in response to various types of findings with respect to the cancer risk posed by new chemicals (or new uses of old chemicals). For clarity, table 1 ignores noncancer risks, and also ignores nondietary cancer risks; in practice EPA would of course consider all risks. (It should be emphasized that discussions in this document of risks resulting from pesticide use are limited to cancer risks due to dietary exposure. It is important for the reader to keep in mind that the EPA's reviews and decisions encompass many other risks as well. Table 1 proceeds from the assumption that all other risk criteria have been satisfied.)

The new approach will affect pesticides in various regulatory categories, as follows:

1. *Pesticides that have no carcinogenic effect or that pose only a negligible risk of carcinogenicity.* For pesticide uses that are the subject of applications for initial registration or for registration for new uses, and that either do not induce cancer in test animals or pose only a negligible human cancer risk (generally a quantitative risk of 10^{-6} or less), EPA will propose to establish section 408 tolerances and section 409 food additive regulations, where necessary, and thereafter approve the applications for registration. Very little scrutiny will be given to the benefits of such noncarcinogenic or negligible-risk pesticides. As it has in the past, the EPA will assume the presence of benefits that outweigh the negligible risk.

Table 1-- Regulatory outcomes under old and new policies

Cancer risk level	Need 409 clearance	Under new policy FFDCA action	FIFRA action	Comparison new vs. old
No risk	No	Issue 408	Register	Same
	Yes	Issue 408, 409 tolerances	Register	Same
Negligible cancer risk	No	Issue 408 tolerance	Register	Same
	Yes	Issue 408, 409 tolerances	Register	Changed: Under old policy, EPA would have refused to issue 408 or 409 or register
Greater-than-negligible cancer risk	No	Issue 408 tolerance if benefit outweighs risk	Register if benefit outweighs risk	Same
	Yes	Refuse to issue 409 because of Delaney: refuse to issue 408 because 409 barred	Refuse to register because of lack of needed FFDCA clearances	Same

2. *Pesticides that pose a carcinogenic risk that is greater than negligible.* Some pesticides may pose a risk of carcinogenicity that is greater than negligible. Generally, such pesticides will be those with quantified upper-bound risks greater than 10^{-6}. (Some pesticides with quantified upper-bound risks greater than 10^{-6} may, however, fall into the negligible- risk category for qualitative reasons, as discussed in the next section.) For pesticide uses not requiring FFDCA section 409 clearances, EPA will continue its current practice of granting FIFRA registrations and the associated FFDCA section 408 tolerances for pesticide uses whose carcinogenic risk is greater than negligible only if the benefits are determined to outweigh the risks based on a careful scrutiny of the projected benefits compared with other available means of pest control. The risks of the available alternative pesticides will be taken into account to determine whether the total risk picture could be reduced by allowing the pesticide on the market. This approach accords with past practice.

3. *Treatment of Group C chemicals.* The chemicals that pose the greatest difficulty in determining the proper regulatory response generally are those that fall into Group C ("possible human carcinogens"). For example, a chemical is placed in Group C if there is some evidence of potential carcinogenicity from animal studies, but that evidence is so limited that the chemical cannot be assigned to a higher category.

   In some cases the EPA will not calculate a quantitative risk for a Group C chemical. Although it is always possible to calculate a quantitative risk number, the EPA believes that in

some cases such quantitative estimates may suggest that the chemical definitely poses a risk to humans, even though in fact the EPA is quite unsure whether the chemical poses human risk.

The Delaney Clause, of course, makes no provision for the weighing of animal-test evidence in terms of its pertinence to human risk. This absolute criterion presents special difficulties with respect to Group C pesticides (possible human carcinogens).

The EPA's treatment for Delaney Clause purposes of a pesticide that falls in Group C will vary. For example, many chemicals fall into Group C merely because the evidence of carcinogenicity comes from only one study. When the evidence from that study clearly indicates a carcinogenic effect in the animal tested, the EPA ordinarily treats the chemical as falling within the "high" end of the C category range and quantifies the risk. A tolerance decision for such a chemical will be based on the quantitative risk number, and the Delaney Clause will be deemed to apply unless the quantitative upper-bound risk level is so low that the chemical's risk may be ignored under the *de minimis* doctrine. Conversely, a pesticide can be classified in Group C because the data on whether the chemical is an animal carcinogen are limited or uncertain; that is, if the data are equivocal, unreliable, or subject to significant doubt, or if only benign tumors occurred. If the EPA determines that the weight of the evidence does not support treating the chemical as an animal carcinogen, the EPA will not treat the chemical as falling under the Delaney Clause.

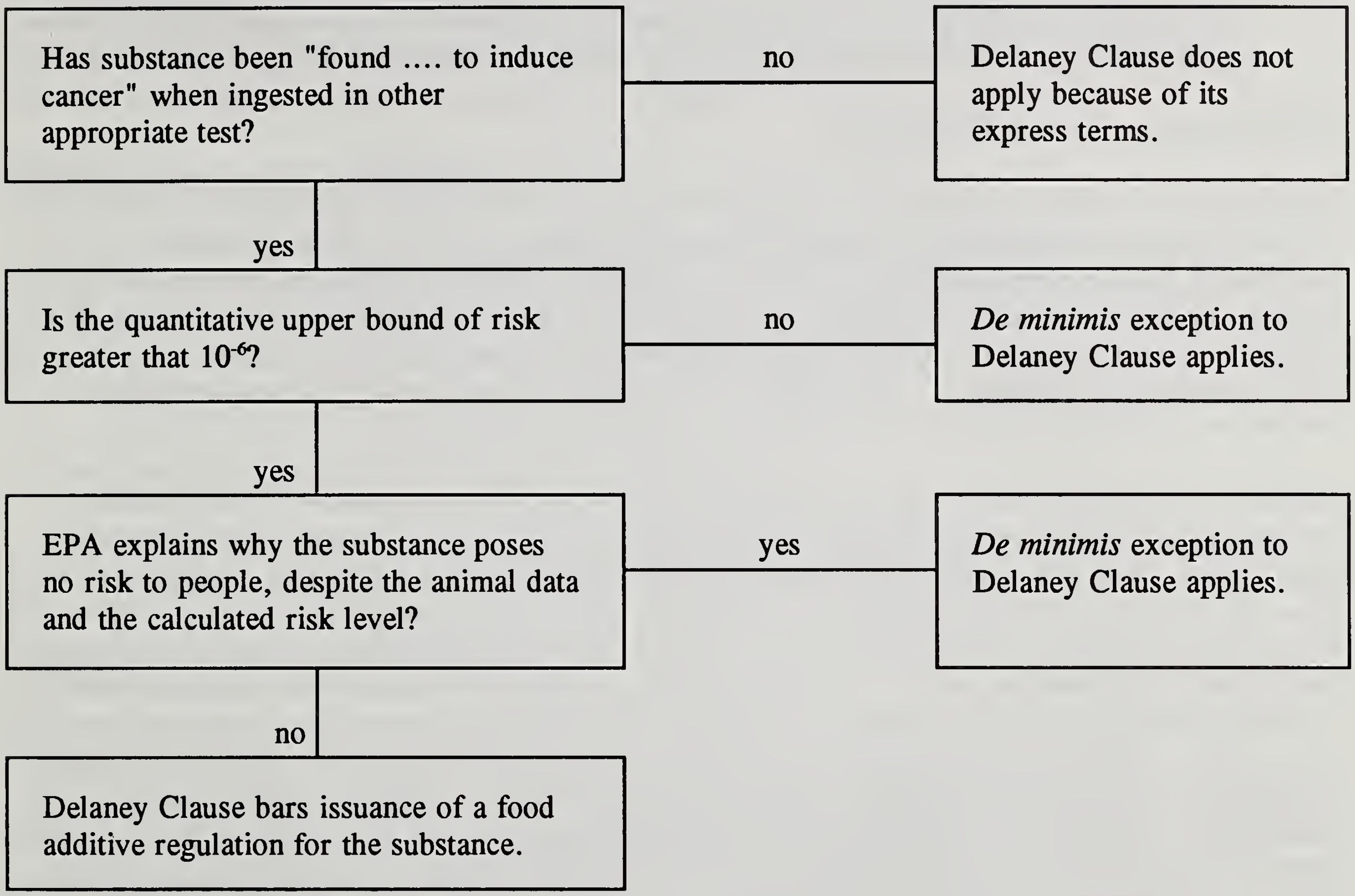
A pesticide may also fall into Group C, not because of any doubt about whether the chemical induces cancer in certain animal tests, but because of uncertainties as to the relevance of the finding to human risk. Reasons for questioning the relevance of the animal data to human risk could include, among other things, known variations in response between the test species and humans, or mechanistic considerations; that is, a showing that cancer was induced in animals only as a secondary effect of an organic change in the animals induced by very high doses of the chemical and a showing that this effect would not occur at the low levels of human exposure.

If a convincing explanation exists for why the chemical poses no risk of cancer for humans, despite the fact that it has been shown to be an animal carcinogen in a feeding study or other appropriate study and has a theoretical upper-bound risk greater than 10^{-6} calculated using a no-threshold model, EPA would propose to treat the chemical as falling into the negligible-risk or *de minimis* category for Delaney Clause purposes because of the qualitative reasons for discounting the animal test results as a predictor of human risk. Given the limited knowledge about interspecies response differences and mechanisms of action for cancer, EPA anticipates that very few pesticides would qualify for *de minimis* treatment on this qualitative basis in the near future.

A Group C carcinogen would be regarded as subject to the Delaney Clause if it did not fall into the quantitative or qualitative *de minimis* exception described in table 2, which summarizes the EPA's proposed treatment of Group C carcinogens.

4. *Currently registered pesticides*. EPA's position with respect to currently registered pesticides that pose at most a negligible dietary risk of cancer will parallel that described earlier for proposed new food uses of pesticides, and the regulatory status of registered pesticides that pose such risks will not be changed. At the other end of the spectrum, EPA is not changing its policy of attempting to cancel FIFRA registrations and revoke FFDCA clearances for pesticides that pose risks of cancer (or other adverse effects) that outweigh their benefits. Finally, EPA is currently determining appropriate procedures to follow with respect to a

Table 2--Decision scheme for Group C chemicals



pesticide whose residues pose an upper-bound cancer risk that is greater than negligible but that is outweighed by the benefits of the pesticide.

5. *Section 18 exemptions*. Section 18 of FIFRA allows EPA to exempt State and Federal agencies from the provisions of the act if the agency finds a consistent approach that should be ideally followed in the regulation of pesticides for food uses, regardless of whether the pesticides are new or old or whether the foods are raw or processed, or the agency finds that emergency conditions exist that warrant the exemption. The changes in the EPA's approach to the issuance of food additive regulations already described in this paper would result in conforming changes in the implementation of the emergency exemption program. The EPA will apply the negligible-risk standard in evaluating emergency exemption requests in a manner similar to other regulatory decisions concerning pesticides that are carcinogens. If associated dietary risks are greater than negligible, the EPA would consider granting the exemption only if the benefits are so great that they outweigh the risks. In this connection, EPA considers, among other things, whether use of the unregistered pesticide would present a lower dietary risk than currently registered alternatives.

6. Minor uses. FIFRA directs the EPA to make the registration process more flexible for minor-use pesticides. Use of the approaches set forth in this paper should favor minor uses

because they ordinarily involve lower exposures than uses of chemicals on major crops, such as wheat or corn.

As with section 18 requests, the need for a section 409 tolerance will no longer be treated as an absolute bar to further consideration of a potentially carcinogenic minor-use pesticide.

Promoting Innovation in Pest Control

Despite gaps in current data bases, there are indications that human health and/or environmental risks exist for many currently registered nematicides and fungicides. In the case of nonfumigant nematicides, product efficacy depends largely on solubility. Solubility, however, increases soil mobility, giving rise to concern regarding ground and surface water contamination. However, the fumigant nematicides also are currently under EPA scrutiny because of potential chronic risks that may be incurred by workers. Of the registered fungicides, 12 are currently undergoing special review, and additional classes of fungicides may be placed in special review in the near future.

The EPA is working with the Agricultural Research Service and the Cooperative State Research Service to focus USDA research efforts on development of alternative controls for nematodes and plant disease. The EPA has identified a particular need for alternative controls for nematodes on citrus and potatoes and for plant diseases on tomatoes, grapes, leafy vegetables, and pome fruits. The EPA is also considering what incentives can be introduced into the registration process to encourage development of alternative controls. These may include waivers of tolerance fees and registration fees for new pesticides that fall into specified categories for which alternative controls are desirable.

The EPA has also joined with USDA, FDA, and private industry to establish a National Pest Management Task Force. The task force will identify those pests of economic significance for which effective chemical controls are no longer available or for which little or no research or registration effort is underway. The task force will develop, in conjunction with member agencies and private associations, mechanisms fostering the development of acceptable control technologies.

Revision of Guidelines and Databases

To improve the efficacy database, the EPA is in the process of revising its Product Performance Guidelines to require the development of "comparative product performance data." In the past, product performance data requirements have concentrated on efficacy data that demonstrate how well a pesticide controls the pests listed on the label. The proposed revisions will require that registrants develop and maintain data that will provide information on performance of a pesticide compared with alternative pesticides, nonchemical techniques, and untreated controls.

Updating Food Consumption Data

The EPA's mainframe-based Tolerance Assessment System (TAS) combines pesticide-commodity tolerance data with food consumption data to estimate possible chemical intake levels. Resources permitting, EPA hopes to update the food consumption data as part of its overall effort to fully implement TAS. EPA hopes to update TAS every 10 years as results of a new USDA survey become available. The EPA also hopes to be able to enhance the analytical capabilities of TAS and to develop statistical guidelines and computer support for the incorporation of more accurate anticipated residue data based on actual residue studies.

Updating Animal Feed Data

Like human food consumption estimates, animal food consumption estimates also need updating. The EPA is working on a project to determine whether byproducts from food processing plants are significant components of animal feeds. Once these significant feed items are identified, percent of diet figures for these new feed items will be determined.

Improved Data for Risk Assessments

To provide for improved data for use in risk assessments, the EPA is developing guidelines and standard evaluation procedures for the use of registrants and food producers in the generation and submission of data to show actual pesticide residues in food. The EPA will also be working with the food industry to develop protocols for processing studies designed to show what happens to pesticide residues during processing.

Reclassification of Raw Versus Processed Commodities

The EPA intends to develop new criteria for classification of commodities as raw or processed in order to update and eliminate inconsistent 408/409 commodity classifications.

Drinking Water Exposure to Pesticides

The EPA is concerned about human intake of pesticides via routes other than food, particularly drinking water. The EPA has historically based its decisions on tolerances only on dietary exposure from foods treated with pesticides. More recently, the Office of Pesticide Programs (OPP) and the Office of Drinking Water (ODW) have begun focusing on drinking water as a potential source of pesticide residues in the diet. The EPA has recently made significant progress in its efforts to integrate activities of OPP and ODW with respect to pesticides in groundwater. All Health Advisories for pesticides in drinking water are now developed jointly by ODW and OPP, using the same database and the same reference dose.

As a part of EPA's implementation of its Agricultural Chemicals in Groundwater Strategy, the agency will be considering the extent to which pesticide residues in drinking water are a significant factor in dietary exposure to pesticide residues. This may be difficult in some cases, but is necessary in order to get a more complete picture of exposure. In cases where pesticides do reach drinking water supplies, it is necessary to factor this exposure into tolerance decisions. For example, exposure to aldicarb through drinking water as a result of its presence in groundwater is being considered in the tolerance assessment in the special review of aldicarb. This is a case in which the data are available, and it is clear that drinking water is a potential route of exposure.

Conclusion

The EPA believes that the recommendations of the NAS offer very useful guidance in improving and refining the process of evaluating pesticides for registration and tolerance purposes. Consistency between the criteria EPA uses in registering pesticides under FIFRA and in setting tolerances for pesticide residues on food under sections 408 and 409 of the FFDCA is a clearly desirable goal. A negligible-risk approach to the pesticide regulatory process would allow the EPA to move in the direction of greater consistency, and allow the registration of new pesticides that pose lower risks than certain currently registered uses.

The EPA also believes it would be desirable to have the authority to review all food additive regulations, as well as tolerances and registration actions, under a risk/benefit standard. Only by

using a risk/benefit standard for all pesticide decisions will the EPA be able to achieve real consistency and have the latitude to properly exercise its judgment based on a consideration of all relevant factors. Such an approach, over the long run, will most likely reduce the total risk attributable to pesticide use. As discussed in this paper, the EPA cannot fully implement this goal without legislative change. Nevertheless, the agency will propose to follow the negligible-risk approach to the extent possible in future rulemakings on individual pesticides.

With regard to the other recommendations of the NAS, the EPA is focusing its energies on reviewing chemicals under a prioritization scheme in order to reduce risks attributable to pesticide use. Finally, the EPA is engaged in developing tools such as the Tolerance Assessment System to refine its ability to make regulatory decisions.

Welfare Implications of EPA's New Registration Standard

The Case of Fresh Market Tomatoes

Walter L. Ferguson

While extensive in its delineation of oncogenicity incidence, the NAS study did not attempt to attach any economic implications to the banning of many widely used pesticides. Depending upon which perspective one takes in evaluating the effect of pesticide use, this is arguably an important consideration. Pesticide registrations under FIFRA have been predicated upon weighing the inherent risks in the use of what had been historically termed "economic poisons," against the economic benefits accruing to the farmer and eventually to the consumer in the form of both an inexpensive and wholesome food supply.

Walter L. Ferguson, USDA/ERS, analyzes the economic implications of different alternative approaches open to the EPA in minimizing carcinogenic or oncogenic (malignant or benign tumors) risk from pesticide use. The benefits of fungicides chlorothalonil and EBDC's are contrasted using the old and new registration standards by assuming the two fungicides are within the negligible-risk category. Similar methodology can be used to assess the short-term implications of bans of registered pesticide uses in other crops. It is not surprising that a total ban of the two oncogenic fungicides on tomato production would result in differing economic implications for those producers previously using the banned fungicides versus the nonusers, and increased consumer prices.

The EPA's October 1988 adoption of a new interpretation of the Delaney Clause could have significant economic implications for growers and consumers. The Federal Food, Drug, and Cosmetic Act, which regulates pesticide residues in food, contains the Delaney Clause thay prohibits the EPA from granting a food additive tolerance for a pesticide if the product is found to "induce cancer" in humans or animals. Under EPA's more conservative interpretation, granting a food additive tolerance is prohibited if the product is found to induce either malignant or benign tumors. This paper illustrates the potential implications on grower returns and consumer costs of a negligible-risk standard for registering or reregistering pesticides. The case is illustrated using fresh market tomatoes.[1]

Findings of a 1987 EPA-supported study by the National Research Council (NRC) indicated that a minor modification of the strict zero-tolerance interpretation of the Delaney Clause could likely lessen the adverse effects of higher production costs and lower yields for growers and consumers, with

[1]The estimates were developed for research purposes and are not an official USDA response to any EPA regulatory action.

negligible effects of oncogenic risks to humans from pesticide residues (*8*).[2] In addition to allowing low-risk alternative pesticides to enter the market to potentially replace current high-risk uses, the merits of the new standard could allow some of the current uses to obtain reregistration if risks do not exceed the negligible-risk standard. The economic implications of a less strict interpretation were not quantified in the NAS study.

In this paper, sensitivity analysis is used to assess the effects of the new standard on grower returns and consumer costs. The analysis employs yield and acres-treated information obtained from extension plant pathologists who work with fresh market tomatoes on a daily basis. The tomato is 1 of 15 food crops which involves a major use of oncogenic fungicides. Three scenarios of oncogenic fungicide bans on tomatoes are analyzed: (1) the loss of chlorothalonil only, (2) the loss of EBDC's (which include mancozeb, maneb, metiram, and zineb), and (3) the loss of both chlorothalonil and the EBDC's. In selection of oncogenic fungicides to be considered using the negligible-risk standard, this paper illustrates use of the EPA's oncogenic evaluation tests, Q* and weight-of-the-evidence, and indicates the short-term benefits and costs of using alternative chemical controls.

The EPA requires a 409 clearance for crops like tomatoes which may be sold in either the fresh or processing markets. Under the old policy, if pesticide residues resulted in a negligible risk, EPA would have refused to issue the 408 or 409 tolerance, or to register the pesticide use (See table 1 of Sisco's article.) For purposes of illustration, this sensitivity analysis assumes chlorothalonil and the EBDC's are within the EPA's current negligible cancer risk level (or within some of the standards currently proposed), and thus would be banned with application of the old standard. That is, the benefits are assessed which producers and consumers would continue to receive if EPA allows reregistration under the negligible-risk standard. If the fungicides are banned or fail to qualify for 409 tolerances under the negligible-risk standard, the estimates reflect the loss of benefits associated with changes in production cost, yield, and price of commodity. (EPA's final decision concerning reregistration of chlorothalonil and the EBDC's is due in 1991.)

Economic Analysis Model

The model used estimates the changes in returns to growers, the increased cost to consumers, and the overall effects to society that result from a pesticide ban and associated higher cost and lower yield. Using the changes in grower profits and price effects as a basis for welfare implications, the changes in grower and consumer surplus are determined by the changes in production costs and yields.

Let us assume that there is a ban of a pesticide causing an increase in control cost to growers and a reduction in yield, as illustrated in part (c) of figure 1. Assessing several scenarios of banned pesticide uses, the short-term economic specifications of the assumption are expressed in equation 1 for a particular crop i + scenario j, where the superscripts b and a refer to periods before and after the ban of a pesticide use with associated loss in yield. Farm-level price elasticities of demand can be used to derive the new equilibrium price to reflect change in production (*3*):

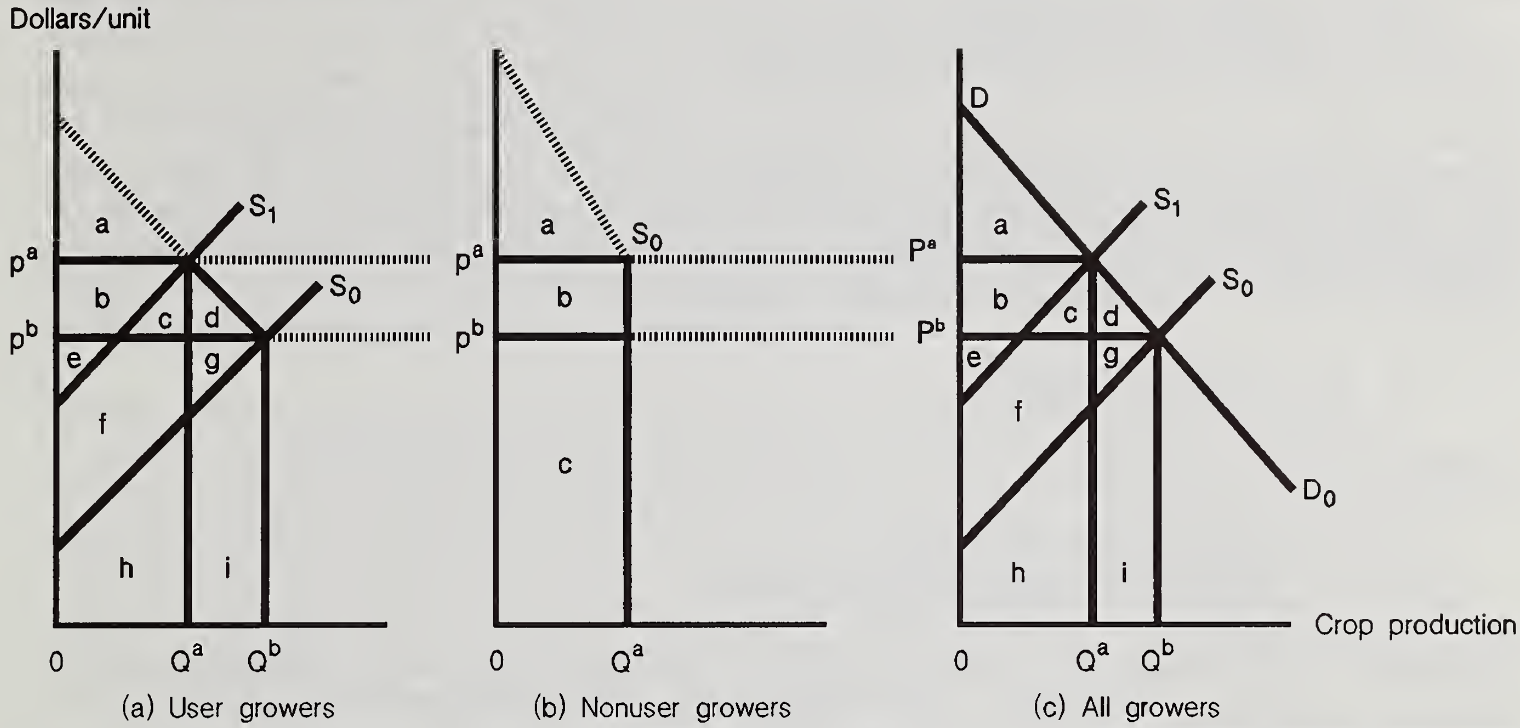
$$P^a_{ij} = P^b_i(1/E_d X_i + 1) \qquad (1)$$

where:

P^a = price after change in production for crop i
P^b = base price for crop i
E_d = price elasticity of demand for crop i
X_i = percent change in production due to infestation for crop i.

[2]Italicized numbers in parentheses refer to items in References.

Figure 1
Effect of pesticide ban



At the initial equilibrium position, with the banned pesticide available, total revenue from the sale of the crop equals P^bQ^b, or area e+f+g+h+i [see fig. 1(c)]. The initial short-term production cost, including a normal profit to growers, is measured by area h+i. Thus, the initial economic profit or surplus accruing to growers equals area e+f+g. A change in grower surplus would occur if use of alternative control results in higher cost and lower yield, as illustrated with supply curve shift of S_0 to S_1. The change in grower surplus, or area b-f-g, equals the change in total revenue, area b+c-g-i, minus the change in total cost, area c+f-i. The change in grower surplus may be positive or negative, depending on the price elasticities of demand and supply curves, and is measured as follows:

$$I^p_{ij} = (P^a_{ij}Q^a_{ij}) - (P^b_iQ^b_i) - (A^aT_{ij}C^a_{ij}) \quad (2)$$

where:

I^p = impact on growers of crop i
P = price per unit of crop (farm level)
Q = total production of crop i, or acres planted x yield
A = acres planted of crop i
T = proportion of planted acres affected of crop i
C = change in control cost per acre for crop i

The short-term implications of higher prices would affect both previous users and nonusers of the banned pesticide. The effect on growers who previously used the pesticide can be determined by the change in surplus on acreage affected by the ban, illustrated by area b-f-g in figure 1(a), and measured by:

$$I^u_{ij} = (P^a_{ij}Q^a_{ij}T) - (P^b_iQ^b_iT) - (A^aT_{ij}C^a_{ij}) \quad (3)$$

where:

I^u = impact on user-growers
T = proportion of planted acres affected

Given perfect elasticity in the market for alternative controls, those growers not having a pest problem or already using the alternatives to the banned pesticide would benefit from the higher crop price without incurring cost increases (fig. 1(b)). The impact on nonuser-growers can be derived by simply subtracting the impact on user growers, from the impact on all growers, or by using a procedure similar to those indicated in equations (3) and (4):

$$I^n_{ij} = (P^a_{ij}Q^a_{ij}R) - (P^b_iQ^b_iR) \tag{4}$$

where:

I^n = impact on nonuser-growers
R = proportion of planted acres not affected

Consumers' total willingness to purchase production Q^b is the entire area under the demand curve between zero and Q^b, or area a+b+...+h+i in figure 1(c). At equilibrium market price, P^b, consumers pay only area e+f+g+h+i. Thus, the net benefit of having the pesticide available is area a+b+c+d. The pesticide use ban results in the loss of consumer surplus area (b+c+d), measured as follows:

$$I^c_{ij} = (P^b_{ij}Q^a_{ij})-(P^a_iQ^a_i)+0.5(P^a_{ij}-P^b_i)(Q^a_{ij}-Q^b_i) \tag{5}$$

where:

I^c = impact on consumers of crop i

The change in consumer surplus associated with a change in price measures the sum of changes in the final-product consumer surplus plus quasi-rents for all industries involved in transforming the commodity traded at the farm level into final consumption form (*5*).

The total change in welfare, or the impact on society, is defined as the change in grower surplus plus the change in consumer surplus (*10*), or area c+d+f+g in fig. 1(c):

$$I^d_{ij} = I^p_{ij} + I^c_{ij} \tag{6}$$

where:

I^d = impact on society

The effect of a pesticide ban is to transfer income from consumers to growers through a higher price due to lower yield in the short term, and passed-on higher production cost in the long term as marginal growers shift out of production.

In sum, a pesticide ban will likely cause a net loss in economic efficiency and a redistribution of income from consumers to growers, with windfall gains to nonuser growers, and gains or losses in benefits to user growers, depending on the crop's price elasticities of demand, and the supply and cost of alternative control.

Ranges Used in Analysis

The benefit analysis employs three fungicide bans with estimated effects of each ban reflecting a range of acres treated, costs, yields, and price elasticities of demand. Average annual estimates of acres planted, yield, and price were derived using 1984-88 published estimates of acres planted, production, and value of production (*11,12,13,14,15,16*).

The base case reflects the: (1) proportion of planted acres treated and changes in yield estimates provided by Extension Service personnel in major producing States who work with tomatoes, (2) cost differentials determined using unpublished estimates and pesticide distributor price lists, and (3) price elasticities of demand developed using published sources (*2,4*).

Although the base case represents the best point estimate, or most likely case, considerable uncertainty of the validity of estimates exists concerning number of acres treated, changes in production cost and yield, and price elasticities of demand. But these estimates nevertheless represent important variables in determining the economic implications of a ban. If based on data from unscientifically designed surveys, however, a point estimate fails to allow for the weakness of the data. It also does not allow for variability of estimates regarding differences in lag times involved when the pesticide is: (1) cancelled or withdrawn from the market, which would allow growers to use their inventories, or (2) suspended, which would prohibit use of inventories.

To address the uncertainty of data estimates and various regulatory policies affecting the lag times involved in making a pesticide unavailable, assessments of regulatory decisions often use arbitrarily set limits to provide a range above and below the base estimates (*1,6*). In this study, a range is developed using arbitrarily set percentages, determined in discussion with extension plant pathologists, of the base estimates provided of the changes in cost, yield, and percentage of acres treated. The arbitrary proportions of base used to derive low and high estimates are shown in table 1.

As indicated, the proportion of the base acres previously treated with the banned fungicide and changes in control cost are assumed to be 0.90 and 1.10 times the base estimate for the low and high scenarios. The low and high estimated changes in yield are derived using a tighter range of 5 percent. The plant pathologists contacted considered the "low" estimate of yield losses unrealistic if 10 percent were used without the use of chlorothalonil or the EBDC's.

Table 1--Coefficients used to derive range of lower and upper estimates

Estimate	Proportion of base estimates	
	Low	High
	Coefficient	
Acres treated	0.90	1.10
Cost	.90	1.10
Yield	1.05	.95
Price elasticity of demand	1.10	.90

Like acres treated, cost, and yield variables, the variations in price elasticities of demand also can cause important differences in estimates of prices and revenues received with changes in crop production. Therefore, due to the variability in published price elasticities of demand, this variable also is included as part of the low and high assumptions to provide a range of values reflecting the variability of economic impact estimates. The range of price elasticities of demand reflects a yield loss having a lesser effect on price in the best case and a greater effect in the worst case.

Assumptions and Limitations

The benefit-loss methodology used in deriving the short-term economic effects that occur during the first year following a fungicide ban entail a number of major assumptions and limitations:

- o As noted earlier, the estimates reflect short-term effects only. Among the longer term mechanisms not included are: biological constraints (such as reduction in the vigor and yield of perennial crops like asparagus and strawberries), increases or decreases in planted acreage, and commodity imports that might substitute for and compete with the domestic crops studied.

- o The economic analysis does not include improvements in applicator safety, environmental safety, or changes in the value of capital assets a fungicide ban might produce.

- o The partial equilibrium analysis does not address effects on substitute crops; for example, losses to producers of crop i may be gains to producers of crop j.

- o Base year acres treated, costs, yields, and price elasticities of demand reflect the average yield of all growers of a specified crop in a typical or average production and consumption year.

- o Yield estimates with use of alternatives take into account the various responses of different cultivars and represent the total crop.

- o The utility of each dollar gained or lost is constant across various economic classes of growers and consumers.

- o The choice of pesticides selected for analysis is based on the pesticides' Q^* and "weight-of-the-evidence" factors. The biases associated with using these measurement factors are elaborated in the following article by Carlson.

- o The effects do not quantify changes involving compensation to farmers and manufacturers for their pesticide inventories, changes in enforcement cost, or changes in demand for alternative pesticides. The supply functions for grower purchased inputs (labor, equipment, alternative pesticides) in each scenario are assumed perfectly elastic.

- o The model is designed to outline the changes in production cost and yield that directly affect growers and consumers of most fruit, vegetable, and specialty crops. It does not take into consideration any indirect price effects on livestock growers and consumers of livestock products, or indirect effect of regulations affecting Government stocks, target prices, and acreage restrictions.

Assessment Crop and Scenario Fungicide Selection

Findings of the 1987 NRC study indicated 80 percent of the estimated dietary oncogenic risk is from the residues of 10 pesticides used in the production of 15 foods. An estimated 90 percent of all fungicides, by volume, are considered by the EPA to be oncogenic or potentially oncogenic,

compared with 60 percent of herbicides, and 30 percent of insecticides. Of the 15 foods accounting for 80 percent of the dietary oncogenic risk, 9 are either fruits or vegetables. The tomato crop accounts for an estimated 15 percent of the total dietary oncogenic risk from the 15-food groups.

The selection of which fungicides to assess is based on the EPA's estimate of each fungicide's oncogenic potency factor, Q*, and weight-of-the-evidence classification. The Q* is based on extrapolation of tumor incidence observed at high doses in animal tests. The weight-of-the-evidence classifies whether the pesticide is "a probable human carcinogen," "a possible human carcinogen," or "not classifiable as to human carcinogenicity." While the Q* estimates only the oncogenic potential, the weight-of-the-evidence considers more qualitative evidence such (as whether tumors are malignant or benign, or whether evident in more than one sex and animal specie). Risk estimates assume residues are at the tolerance level, that 100 percent of all acres are treated, and that exposure occurs over a 70-year lifetime. Under these conservative assumptions, chlorothalonil and each of the EBDC's are given ratings of relatively high oncogenic potential (Q*). Although a weight-of-the-evidence rating is not available in the NAS study for chlorothalonil, each of the EBDC's (based on EBDC metabolite ethylene thiourea) is rated by EPA as a probable human carcinogen. It should be emphasized that these qualitative ratings are based on highly conservative assumptions to allow a buffer safety zone.

Results

The benefits of the negligible-risk standard are illustrated by banning two fungicides, chlorothalonil and the EBDC's, on fresh market tomatoes, under the zero-risk standard and assuming the registered uses of these fungicides will continue under the new standard. The scenarios used to illustrate the short-term economic implications of the bans on producers and consumers are as follows:

1. The loss of chlorothalonil only.
2. The loss of EBDC's (mancozeb, maneb, metiram, and zineb).
3. The loss of both chlorothalonil and the EBDC's.

In addition to the base case analysis, the effects of each scenario's ban reflects "low" and "high" estimates, as indicated earlier in table 1, to allow for uncertainty of data and use of pesticide inventories. For example, the Scenario I impacts of a chlorothalonil ban indicate the base estimate that reflects acres treated, control costs, and other estimates based on published and unpublished sources, and low and high estimates based on arbitrarily selected coefficients.

Chlorothalonil is the singularly most extensively used oncogenic fungicide on fresh market tomatoes, with a base of 75,000 treated acres or about 58 percent of the total 129,000 planted acres (app. table 1). The EBDC's, as a group, represent both extensively and intensively used oncogenic fungicides on fresh market tomatoes with an estimated 74,000 acres treated with any of the EBDC's. Scenario III reflects use of alternatives on an estimated 70 percent of the planted acres treated by either chlorothalonil or the EBDC's.

The use of alternatives to chlorothalonil would increase cost by $3.20 per acre in the base case. The alternative chemical controls to chlorothalonil include the EBDC's, copper hydroxide, copper sulfate, triadimefon, benomyl, metalaxyl, and sulfur. Control cost with a chlorothalonil ban would increase by less than $0.3 million on acreage previously treated with chlorothalonil (app. table 2). An EBDC ban, using chlorothalonil and the other alternatives would increase treatment cost by about $8.50 per acre, or a total of less than $1 million. Without either chlorothalonil and the EBDC's, treatment control using the alternatives would increase cost by $13-$16 per acre, or $1-$1.6 million total.

Using alternative control, hypothetical U.S. average yield losses of 10, 15, and 20 percent are assumed on the acreage previously treated with the respectively banned fungicide scenarios: chlorothalonil (I), EBDC's (II), and both (III). Using these assumed losses, the 1984-88 base yields for fresh market tomatoes would drop from 271 hundredweight (cwt) per acre to 244 cwt, 230 cwt, and 217 cwt (app. table 3). As stated previously, these estimates of changes in yield assume an "average year" with no atypical extremes in weather or disease outbreaks.

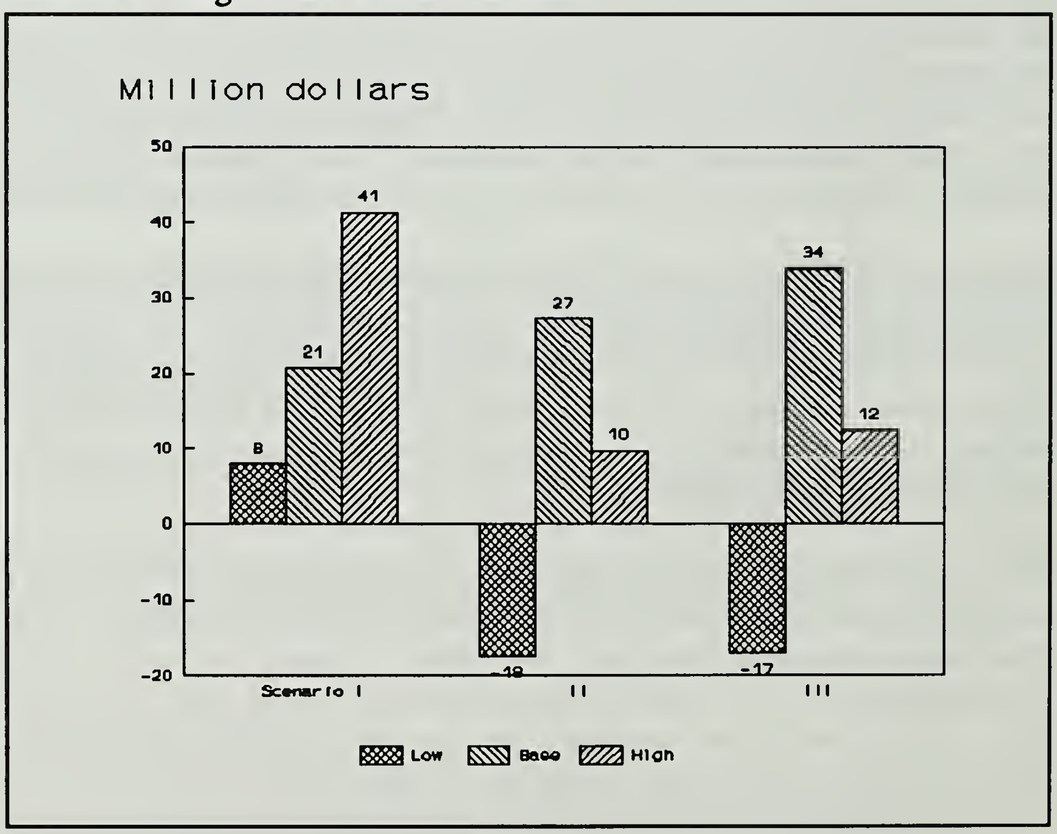
With the arbitrary yield losses and a price elasticity of demand of -0.67 in the base case, fresh market tomato prices would increase from a 1984-88 average of $25.45 per cwt to $27.66 per cwt with a chlorothalonil ban, or a 9- percent price increase. An EBDC ban would result in an estimated price increase of 13 percent, and a ban on both chlorothalonil and the EBDC's would result in a price increase of 21 percent.

The lower yields and associated higher prices would result in changing revenues to all growers, which include the users and nonusers of the banned fungicides. A chlorothalonil ban would increase grower revenues by an estimated $8-$41 million (fig. 2). An EBDC ban would change grower revenues ranging from a decrease of $18 million to an increase of $27 million. Banning both chlorothalonil and the EBDC's would change grower revenues ranging from a decrease of $17 million to an increase of $34 million.

For previous users, a ban would result in short-term decreases in revenues to these growers as a result of reductions in yield and higher control cost (fig. 3). A chlorothalonil ban would result in an estimated $8-$12 million decrease in grower revenues, and an EBDC ban a $21-40 million decrease. Banning both fungicides would result in $22-$47 million losses in revenues. It should be emphasized that these estimates represent short-term effects. For example, in the longer term, if diseases were not adequately controlled, yield losses could be considerably higher than the 20 percent indicated in the case of using alternatives to chlorothalonil and the EBDC's (*9*).

For nonuser growers, the higher tomato prices with no change in yield would result in windfall gains, ranging from $17-$49 million in increased revenue with the Scenario I ban of chlorothalonil, and about the same effect with an EBDC ban (fig. 4). A Scenario III ban of both chlorothalonil and EBDC would effect nonuser growers with $30-$56 million in increased revenues. The base estimate exceeds the high estimate due to the assumption of nonuser growers having 10 percent less affected acreage in the high case.

Figure 2
Returns to all growers: Fresh tomatoes



A ban on chlorothalonil or the EBDC's would result in increased costs to consumers of fresh market tomatoes by about $34-$130 million (fig. 5). A ban on both chlorothalonil and the EBDC's would result in cost increase of $79-$202 million to all consumers in the short term, both domestic and foreign. Domestic consumers of an estimated 97 percent of the crop would incur cost increases of $76-196 million (app. table 7).

The total effect of the scenario bans on producer revenue and consumer cost, or the effect on society, would range from $26-$89 or $51-$119 million losses in benefits for chlorothalonil or EBDC bans. Losses would be $96-$190 million with a ban on both chlorothalonil and EBDC (fig. 6).

It should be emphasized that the illustrated effects reflect bans on registered uses of only one crop. Chlorothalonil and the EBDC's, however, are widely used fungicides with major uses in many fruit, vegetable, and specialty crops. Thus, the implications of the *de minimis* standard are that economic losses would be significantly reduced if:

Figure 3
Returns to user growers: Fresh tomatoes

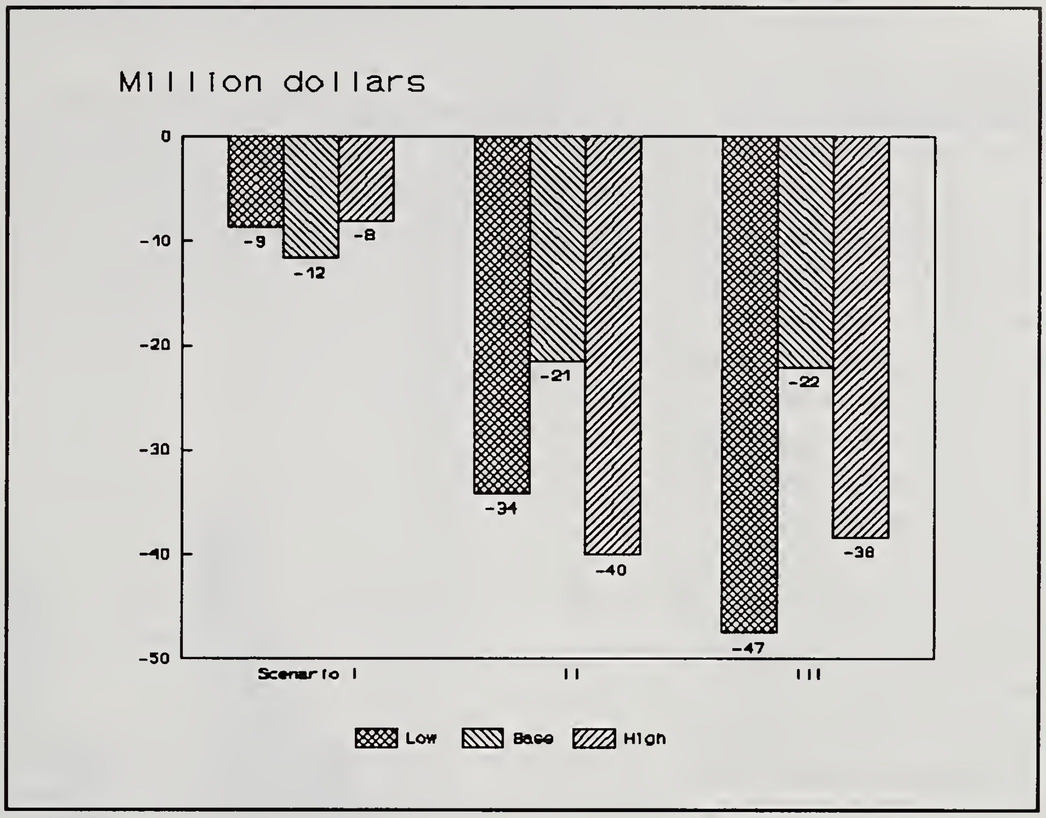
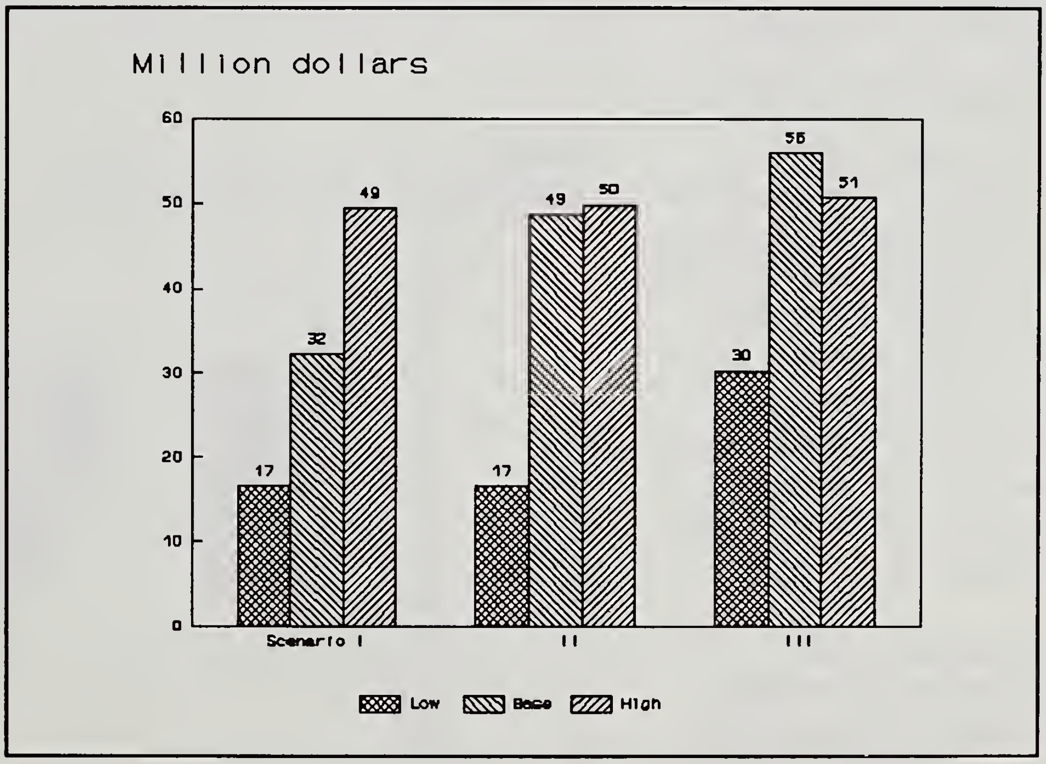


Figure 4
Returns to nonusers: Fresh tomatoes



(1) the new standard allows either EBDC's or chlorothalonil to remain on the market, while both would have been banned under the previous standard (that is, if *de minimis* allows more alternatives to remain on the market), or

(2) the new standard allows new alternatives of comparable or better cost-effectiveness to EBDC's or chlorothalonil, but with less risk, to be registered, while the previous standard did not.

Summary and Potential Implications of New Standard

The potential economic implications of fungicide bans are examined, for growers and consumers of fresh market tomatoes, under the new negligible-risk tolerance standard. Chlorothalonil and the EBDC's are each used to treat nearly 60 percent of the planted fresh market tomato acreage. The benefits of the negligible-risk interpretation of the Delaney Clause are illustrated using three scenarios under the previous zero-risk standard: (1) chlorothalonil, an extensively used oncogenic fungicide, (2) EBDC's, which represent as a group, both an extensively and intensively used oncogenic fungicide, and (3) both chlorothalonil and EBDC fungicides. The three scenarios take into account estimated short-term changes in cost and yield on the acreage treated with the oncogenic fungicides.

In addition to the reregistration of highly effective pesticides that have minimal or negligible adverse effects on human health and the environment, the new standard could likely enhance the market for new pesticides, an effect especially needed by some

Figure 5
Change in consumer cost: Fresh tomatoes

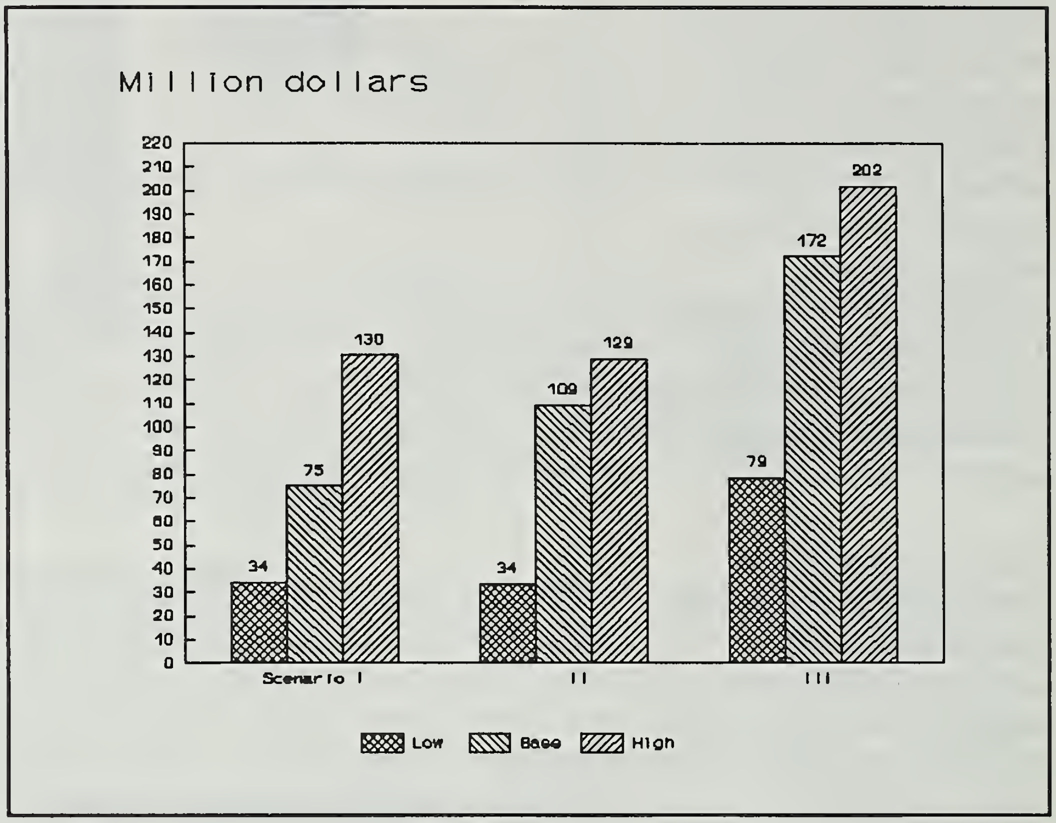
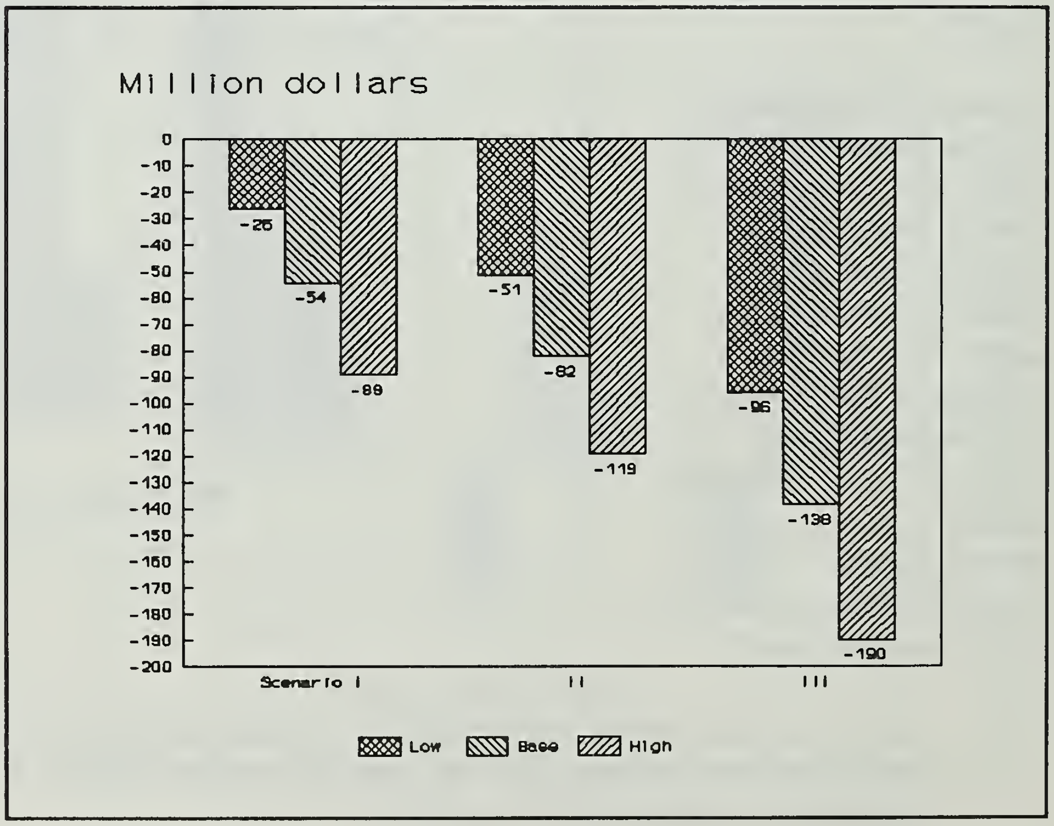


Figure 6
Total impact, growers and consumers



producers of fruits, vegetables, and specialty crops. The potential for maintaining pest control and associated yield using new pesticides and reregistration of effective currently used pesticides could dampen the adverse short-term effects of a pesticide ban on food prices and grower revenues.

In the long term, the negligible-risk standard could help growers avoid pest resistance problems that generally occur with fewer alternative chemical controls. If higher yield can be associated with enhanced availability of alternative chemical controls, then use of the new standard could have a favorable effect on the U.S. balance of trade by lowering imports of some crops, while allowing no increase or a negligible increase in cancer risk.

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Appendix table 1--Fresh market tomatoes: Proportion of U.S. planted acres treated and change in production cost per acre[1]

Scenario	U.S. average planted acres 1984-88	Low		Base		High	
		Proportion of U.S. acreage treated	Change in production cost/acre	Proportion of U.S. acreage treated	Change in production cost/acre	Proportion of U.S. acreage treated	Change in production cost/acre
	1,000 acres	*Percent*	*Dollars*	*Percent*	*Dollars*	*Percent*	*Dollars*
I	129	0.52	2.88	0.58	3.20	0.64	3.52
II	129	.52	7.65	.57	8.50	.63	9.35
III	129	.63	13.14	.70	14.60	.77	16.06

[1]Fungicide ban(s), by scenario:
I: Chlorothalonil
II: EBDCs (mancozeb, maneb, metiran, zineb)
III: Chlorothalonil, EBDCs

Appendix table 2--Fresh market tomatoes: Projected U.S. acres treated and change in total production cost[1]

Scenario	Acres treated			Change in total production cost		
	Low	Base	High	Low	Base	High
	--------- *1,000 acres* ---------			-------- *1,000 dollars* --------		
I	68	75	83	194	240	290
II	67	74	81	509	629	761
III	81	90	99	1,064	1,314	1,590

[1]Scenarios defined in footnote 1, appendix table 1.

Appendix table 3--Fresh market tomatoes: 1984-88 U.S. average and projected yield[1]

Scenario	1984-88 yield	Yield on affected acres		
		Low	Base	High
		Hundredweight		
I	271	256	244	232
II	271	242	230	219
III	271	228	217	206

[1]Scenarios defined in footnote 1, appendix table 1.

Appendix table 4--Fresh market tomatoes: 1984-88 U.S. average and projected production[1]

Scenario	1984-88 production	Proportion of crop exported	Production, using alternatives--		
			Low	Base	High
	1,000 cwt	*Percent*	*1,000 cwt*		
I	34,959	0.03	33,953	32,927	31,717
II	34,959	.03	33,966	31,951	31,760
III	34,959	.03	32,599	30,081	29,794

[1]Scenarios defined in footnote 1, appendix table 1.

Appendix table 5--Fresh market tomatoes: 1984-88 U.S. average and projected price[1]

Scenario	1984-88 price	Price elasticity of demand			Price, using alternatives		
		Low	Base	High	Low	Base	High
	Dollars/cwt	*Coefficient*			*Dollars per cwt*		
I	25.45	-0.74	-0.67	-0.60	26.44	27.66	29.36
II	25.45	-.74	-.67	-.60	26.43	28.72	29.31
III	25.45	-.74	-.67	-.60	27.78	30.75	31.69

[1]Scenarios defined in footnote 1, appendix table 1.

Appendix table 6--Fresh market tomatoes: Projected change in U.S. grower returns with fungicide ban, users and nonusers[1]

Scenario	Change in revenue, all growers			Change in revenue, users			Change in revenue, nonusers		
	Low	Base	High	Low	Base	High	Low	Base	High
	Million dollars								
I	8	21	41	-9	-12	-8	17	32	49
II	-18	27	10	-34	-21	-40	17	49	50
III	-17	34	12	-47	-22	-38	30	56	51

[1]Scenarios defined in footnote 1, appendix table 1.

Appendix table 7--Fresh market tomatoes: Projected change in consumer costs with fungicide ban, domestic and foreign consumers[1]

Scenario	Change in cost, all consumers			Change in cost, domestic consumers			Change in cost, foreign consumers		
	Low	Base	High	Low	Base	High	Low	Base	High
					Million dollars				
I	34	75	130	33	73	127	1	2	4
II	34	109	129	33	106	125	1	3	4
III	79	172	202	76	167	196	2	5	6

[1]Scenarios defined in footnote 1, appendix table 1.

Appendix table 8--Fresh market tomatoes: Projected total impact of fungicide ban[1]

Scenario	Change in revenue, all consumers			Change in cost, all consumers			Total impact		
	Low	Base	High	Low	Base	High	Low	Base	High
					Million dollars				
I	8	21	41	34	75	130	-26	-54	-89
II	-18	27	10	34	109	129	-51	-82	-119
III	-17	34	12	79	172	202	-96	-138	-190

[1]Scenarios defined in footnote 1, appendix table 1.

Risk Assessment and Regulatory Priorities for Pesticide Residues in Food

Gerald A. Carlson

Movement by the EPA toward a consistent approach in dealing with registration of pesticide compounds that contain some level of oncogenic risk was initiated based upon recommendations of a NAS risk assessment study. The 2-year study was commissioned by the EPA to aid it in reconciling the oft times paradoxical stipulations of FIFRA and the FFDCA.

As a member of the committee formed by NAS to carry out the assessment, Gerald A. Carlson, professor of agricultural economics at North Carolina State University, is in a unique position to discuss the procedures and assumptions adopted by the committee in arriving at policy recommendations. A number of these assumptions have been extensively criticized by individuals representing production agriculture and agribusiness interests as having no relevance to actual production practices. Dr. Carlson warns that a cautionary approach should be adopted when using these recommendations for setting regulatory priorities. His monograph provides an outline of the theoretical framework upon which the risk assessment was constructed, as well as the caveats necessary in interpreting the results and defining policy implications.

The National Research Council Committee on Scientific and Regulatory Issues Underlying Pesticide Use and Innovation spent about 2 years preparing a report on regulating pesticide residues in food. The major focus was on providing assessment of options that the Environmental Protection Agency (EPA) had in protecting public health under the 1958 Delaney Clause. However, the committee (Delaney Committee) was also charged with examining effects of regulatory changes on the availability of currently marketed agricultural pesticides and incentives to develop new pesticides (*9*).[1]

Several technical and legislative changes are pushing pesticide residue problems to prominence. The capability to detect minute quantities of pesticides in food has expanded rapidly in recent years. At the same time, the 1978 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) require that all pesticides be reregistered. A strict interpretation of the Delaney Clause is likely to be a barrier to reregistration for many widely used pesticides which currently have tolerances for food uses. Both the economic and public health consequences of various ways to meet the zero cancer-risk features of the Delaney Clause are at the heart of the current policy debate.

From an economic standpoint, most of the inconsistent regulation of some pesticides versus others stems from the fact that FIFRA and the raw agricultural products (section 408) part of the Pure Food and Drug Act are benefit-risk statutes, whereas, the Delaney Clause (part of section 409) is a risk-only law that does not allow "risk-risk" tradeoffs, such as pesticide versus aflatoxin, or economic benefits to be weighed against cancer risks when evaluating pesticide residues in certain processed

[1]Italicized numbers in parentheses refer to items in References.

food. Because it is difficult in practice to separate food destined for processed from nonprocessed forms, any pesticide shown to be a potential oncogen (tumor causing) may be restricted under rigid interpretation of the Delaney Clause.

In order to assess the likely effects of the Delaney Clause on the availability of and potential oncogenic risks from pesticides, the Delaney Committee conducted a "risk assessment" on a set of 28 suspected oncogenic pesticides with food tolerances (legal maximum residues). This assessment gave estimates of risk levels and rankings for food crops and pesticide groupings, and served as the basis for comparing four different regulatory alternatives in the study. Risk in this case means the change in frequencies of all tumors from "worst case" lifetime exposure to pesticides (described more fully below). Risk assessment is of growing importance in use decisions for pesticides for food, water, and labor safety, but methods are not standardized (*10*).

This paper discusses the procedures and assumptions made in the risk assessment in the Delaney Committee report. As a member of the committee, I suggest that great caution is warranted in using this particular risk assessment for setting regulatory priorities. Assumptions were made in order to reflect how the EPA assesses risk so that predictions could be made about which pesticides would likely be affected by the Delaney Clause. Thus, the committee was not trying to assess risks; it was trying to assess how the regulatory process under EPA would likely assess risks. Consequently, many conservative assumptions were adopted.

Agencies with regulatory and information-providing responsibilities such as EPA, State pesticide authorities, U.S. Department Agriculture, and land grant universities must set budget priorities in regulating pesticides. Because most EPA regulatory actions are made on specific pesticides on specific crop uses, priorities on which pesticides or which crops are to be evaluated are paramount. However, concerns about other sources of pesticide risk besides food (water, direct occupational), noncancer problems (acute toxicity, neurological, environmental), and selection between policy instruments should not be ignored in a comprehensive review of regulations. The Delaney Committee's risk assessment did not explicitly consider policy instruments that EPA currently uses (such as altering food and food tolerances), changing label requirements (location, timing, and maximum dosages), and many other regulations (reregistration fees, minor use subsidies, or residue cleanup). The "worst case" or maximum legal "regulatory risk assessment" of only 28 pesticides provided by the Delaney Committee is only a part of the information needed to set broad, regulatory priorities. In this paper, I review analytical models of pesticide regulations, outline the procedures and likely errors of the risk assessment of the Delaney Committee, and discuss other factors the committee uncovered related to regulatory priorities.

Pesticide Assessment Models

Before examining the Delaney Committee risk assessment model, I find it helpful to consider three groups of models that provide perspective and information for risk assessment models: (1) pesticide use or farmer demand models, (2) biophysical pesticide fate models, and (3) consumer-producer welfare models. Risk assessment models are most closely linked to consumer welfare models, but they also depend on estimates of pesticide use and movement of pesticide residue to determine baseline exposure levels.

A pesticide use model for a specific pesticide or pesticide category can be represented by an individual farmer's decision to control pests by purchase and use of the pesticide (X_i). This depends upon area planted to a set of crops (A), physical features (B) (such as pest level, weather, and soil type), prices of the pesticide (PX_i), pesticide substitutes (PX_1), and nonpesticide (PZ) substitutes, crop prices (PY_j) and the use limits for various regulatory instruments (R_k). Most pesticide demand studies assume that the safety to the farmer or other handlers of a particular pesticide is not very critical, but

this factor may need to be included as well. A representation of a demand model for the use of pesticide i on crop or food j (X_{ij}) would be

$$X_{ij} = f(A_i, B, PX_i, PX_1, PZ, PY_j, R_k) \quad (1)$$

All factors except price of the pesticide (PX_i) would tend to increase pesticide use. Regulatory actions under the Delaney Clause would affect the total universe of pesticides available and hence the prices of other pesticides (PX_1), whereas other FIFRA regulations would change use through legal limits (R_k). There are only a few examples of this type of model in the literature because of lack of data on pesticide use. Studies by Miranowski (7) and Carlson (3) emphasize input and output price effects, while Osteen and Kuchler (6) treat the substitution effects of selective pesticide restrictions (R_k).

Models of how pesticides move from points of use to food, water, and other media are primarily descriptions of complex physical and chemical reactions. A representative model is

$$X_{ij}^c = g(X_{ij}, RM_j, W, S, CP_{ij}, FP_j) \quad (2)$$

in which X_{ij}^c is the concentration of pesticide (i) in a food ($_j$) or other media, X_{ij} is the use level from model (1), RM_j represents the residue management activities of farmers such as cropping practices, or use of various crop parts for animal feed, W represents weather events, S refers to the site characteristics (soil type, slope, water table level, and others), and CP_{ij} refers to the chemical-physical degradation and mobility properties of each pesticide in food j. Food handling and processing (FP_j) at each stage of the marketing system, including home preparation, can change residue levels. There are various pesticide transport models, but most of them are local in nature and they may not be very robust in predicting residue levels in media under wide ranges of environmental conditions (*2,4*).

Finally, the welfare models measure the effects of pesticide residues on consumer and producer welfare. Equation (3) shows a general welfare model with U representing consumer utility, in which $\Sigma\Sigma X_{ij}^c$ is the total residues of all pesticides in all media (all food, water), C_j represents consumption level of food $_j$ for the typical person, D_i is potency of the pesticide residues in causing health damages or risks (dose-response slope), MS represents the margin of safety that consumers desire, and PY_j represents other welfare considerations represented by the price of the foods involved, to give

$$U = h(\Sigma\Sigma\, X_{ij}^c\, C_j, D_i, MS, PY_j). \quad (3)$$

Increases in each of these factors, except food consumption and the margin of safety, will decrease consumer welfare. The utility function does not account for environmental effects of pesticide use such as wildlife damage, but these could be included if the risk assessment were broadened beyond food and water consumption effects. For cancer risk, the potency is the cancer potency factor of a given pesticide. In the Delaney Committee risk assessment, this potency (Q^*) was assumed to be the marginal tumor incidence from a lifetime exposure of the pesticide, measured as the upper 95-percent confidence interval values for the extra tumors from exposure to a given pesticide extrapolated (for bodyweight and lifetime) from animal feeding studies (*9*).

With this background we can write an expression for the Delaney Committee risk assessment as

$$R_i = m(\Sigma\Sigma X_{ij}^c \,.\, C_j \,.\, Q_i^*). \quad (4)$$

Where R_i is the extra probability of obtaining a tumor from exposure to food residues of pesticide i from all foods, X_{ij}^c are the pesticide residues that are set equal to the maximum legal or tolerance levels for each registered use on each food, j, C_j is the average consumption level of all foods for

which the pesticide has a use registration, and Q_i^* is the frequency of extra tumors from animal feeding studies for pesticide i. Each factor increases the chance of an individual developing a tumor, and the factors enter in a multiplicative form. Risks for specific foods (R_j) can also be calculated by summing over all pesticides used on a particular food crop ($\Sigma\Sigma X_{ij}^c$).

Potential Errors in the Delaney Committee Risk Assessment

Each of the four components of the risk assessment (use level, residue concentrations, consumption, and potency) is likely to be measured with error. Because of lack of data and because the EPA safety margin procedures were followed, there are reasons why tumor risks measured using model (4) might be either under- or overestimated. The data assumptions and procedures are described in terms of how they would lead to over- or underestimates of risks for the typical consumer for each of the four components.

Total change in oncogenic risk is likely to be underestimated for two reasons related to pesticide use (X_{ij}). First, total risk was based on 28 of the 53 suspected oncogenic pesticides because of lack of tests to obtain Q* for the other 25 compounds. Second, there may be some inert materials in pesticide compounds that are also oncogenic which were not included. However, some of the major metabolites that are oncogenic were included, and the 28 compounds that were included constitute some of the most widely used pesticides.

There are also important reasons to believe that the use levels of the 28 included pesticides are overestimated. In the absence of complete use data, it was assumed that residues of all 28 pesticides equaled tolerance levels, which, in turn, implies that all 28 pesticides were used on every acre of every crop for which they were registered. Many of the pesticides are substitutes for one another. If one fungicide were used, another one would not also be used in many cases. More importantly, many of the 28 pesticides are older pesticides and have many registered uses for which they are no longer used, or used only on a small part of the crop area. For example, linuron is an older herbicide registered for use on corn, wheat, and other crops, but current use surveys show no use except for soybeans and a few minor acreage crops. Yet the use on every crop acre registered carries forward residues as if million of tons of major crops and livestock were contaminated with this compound. The same exaggeration is true for each of the older compounds that have many registered uses for which there is little or no use today.

There are also identifiable biases in the assumed residue levels of each pesticide per unit of food (X_{ij}^c). As indicated above, because of lack of actual food residue data, the Delaney Committee assumed that all food had the legal maximum residues of each pesticide or the tolerance levels. This could lead to some underestimates because EPA does not currently recognize all possible livestock feeds and establish tolerances for them. Feed additives are generally regulated under the "sensitivity of the method" procedure rather than the more stringent section 409 procedures. Similarly, EPA assumes that some foods (peanuts for example) and most dairy, meat, and poultry products have no processed forms. Therefore, no section 409 tolerances are present for the processed forms of these products, providing a potential source of underestimation of the total pesticide residues.

On the other side of the ledger, assuming residues present in all foods at the tolerance levels greatly exaggerates actual residues. In the early years (1950-72) of pesticide registration, tolerances were often set at high levels to prevent frequent confiscation of produce with pesticide residues above tolerances. The usual procedure in setting tolerances was to apply pesticides at the maximum dosage needed to control high pest infestations, harvest it early, and focus on the very highest residue concentration found in food samples. This or some multiple of it was the tolerance. Because of this procedure, most older tolerances are 10 to 1,000 times actual residues on food as purchased. A further reduction in residues occurs if storage, food processing, or food preparation (washing,

peeling, cooking) reduces residue as eaten. The magnitude of the overestimate due to assuming all food has tolerance level residues is illustrated by a survey statistic from the Government Accounting Office, which shows that more than 50 percent of all stratified random samples of food taken by the Food and Drug Administration (FDA) have no pesticides residues at all (5). This proves to be the case even though the FDA has policy of oversampling foods and locations (stratifications) where problem residues were found in the past.

The procedure used in the risk assessment to convert pesticide residues per unit of food into consumption levels was to multiply tolerance levels of residues by the "food factor" in the diet of the average U.S. person. To account for variability in consumption, the committee used the upper 95-percent confidence interval food weight for each of 273 food forms in the 1977-78 USDA consumption survey (*9*). Clearly, this procedure may underestimate because it does not account for some consumer groups that eat large amounts of some foods (vegetarians, babies) or account for high consumption regions (Californians eating more vegetables and fruit). These groups might have more exposure to some pesticide than the average consumer.

However, there are also major overestimates of all exposure levels by using 95-percent confidence interval food weights, ignoring food substitutions, and assuming that all food has the same contamination levels regardless of where residues are usually found. The 95-percent confidence interval values of all foods are about two to four times as large as average values. Also, most individuals substitute one form of a food for another, whereas the risk assessment assumed consumption of each form of the food. For example, each person is assumed to consume apple juice, applesauce, and fresh apples equal to the 95-percent confidence interval weight for each apple type. More importantly, beef, pork, and poultry livers are sometimes the only organ in which a particular pesticide residue has been found. Yet, the procedure used assumes all meat has the residue. In fruits and vegetables, pesticide residues may be concentrated in the skin, which is peeled or cooked off. Yet, the full weight of the product is assumed to be contaminated. Overall, it is likely that food exposure (food consumption times residue concentration) is much lower than tolerance levels on all foods.

The final risk component is the change in tumor incidence or potency (Q^*). The procedure followed was to use EPA estimates of pesticide potency. This is the upper 95-percent confidence interval of the probability of tumors developing with a change in pesticide exposure in the diet. These values are based on extrapolation from high dosages fed to animals and adjusted for body weight and assuming lifetime (70 years) consumption. These tests do not consider interaction between pesticides, so this may be a source of underestimation or overestimation, as we do not know how interactions affect oncogenicity.

There are many sources of over estimation in Q_i^*. First, there may be spontaneous tumor developments or other tumors "induced indirectly" because of high dietary levels used in tests to measure potency. This factor may help explain the high rate of tumor development for fungicides, herbicides, and plant growth regulators which are not as acutely toxic as insecticides. The plant compounds must be fed at high proportions of the diet inducing tumors by volume, or allowing more time for tumors to develop in mammalian test animals. In addition, some pesticides may be associated with one, but not all three phases of the mutation-promotion progression process of cancer development (*1*). Finally, linear extrapolations will tend to exaggerate the potency if the process of tumor development alternates between a linear upward and plateauing effect. All of these uncertainties have led EPA to use "weight of the evidence" evaluations rather than Q^* values for their cancer assessments for pesticides. The FDA resorts to a narrower definition of a carcinogen in administering the Delaney Amendment for food additives other than pesticides.

There is no way to know how large the biases are for each component in the Delaney Committee risk assessment. However, the sources of overestimation are obvious and clearly large for most foods and pesticides. The baseline lifetime risk of cancer among U.S. citizens is about 0.25 or one in four. The incremental risk from the 28 pesticides taken together was estimated to be 0.0058. Therefore, even this "worst case" estimate showed pesticides on food are associated with less than 3 percent of all cancers.

Risk Assessment and Regulatory Priorities

A major emphasis of the Delaney Committee study was to find which crops and pesticide types were associated with pesticide residues. The risk assessment results showed that 60 percent of the total oncogenic risk was from fungicides, 27 percent from herbicides, and 13 percent from insecticides. Much of the risk is estimated to be associated with older compounds, and only 15 food crops account for 80 percent of the dietary risk. Should this information be used to select pesticides and crops for regulatory action?

Because of assumptions made in the study, there are reasons suggesting that the risk-assessment procedure itself tends to exaggerate the dietary risk from older pesticides, and, therefore, should not be used in setting regulatory priorities. First, given the calculation methods used, older pesticides which typically have more registered uses will have higher risks regardless of how much of the pesticide is used. If risks had been related to pounds used and proportion of a crop treated, then many older pesticides may be ranked lower in terms of total risk. Similarly, as discussed above, new pesticide products tend to have tolerances set closer to actual residues. Using tolerances to estimate residuals per unit of food has exaggerated exposure risks more for older than newer compounds.

There is a tendency for foods with many pesticide tolerances to have high ranking as sources for oncogenic pesticides. This is largely related to number of tolerances or pesticides used on a particular crop, not amounts of pesticides used per unit of food consumed. Crops with large acreage and higher pest damage tend to have more registered pesticides than do minor use crops. The focus of the Delaney Committee on tolerances undoubtedly biases risk estimates toward a few major crops or food types.

The Delaney Committee had good suggestions on equal regulatory treatment of pesticides regardless of when they were registered or regardless of whether they are used on foods consumed in processed or raw forms. However, the emphasis on older compounds or high-risk compounds may be misleading given the method of estimating exposure risk. The high proportion (60 percent) of risk associated with fungicides may follow from applicability of animal models for human toxicity, such as the toxicity of fungicides versus insecticides in animal feeding studies.

From an economic benefit standpoint, there are often very important reasons for retaining the use of older compounds. First, they often are much less expensive than newer pesticides. Fungicides such as captan, organochlorine insecticides, and simple herbicides such as 2,4-D are widely used throughout the world because they save long hours of hand weeding and control insect and disease damage at very low costs. Because of the relatively higher labor cost, U.S. farmers of some crops could be put at considerable disadvantage in foreign and U.S. markets if they could not use these pesticides. Second, once farmers learn to use particular pesticides, there are high costs of changing to new ones. Management and application costs are often high relative to material costs. Finally, older compounds are an important component of a diversified portfolio of chemical and non chemical approaches to reducing pesticide resistance development (*8*).

The EPA has a difficult task in implementing reregistration procedures that protect human health without disrupting pest management practices. It does not and should not focus on Q^* measures of

pesticide potency. It must examine all sources of human exposure to pesticides and not just oncogenic risks from food residues. There should be a willingness to use a broad range of use restrictions besides complete cancellation for the "high-risk" pesticides.

One regulatory procedure discussed at length by the Delaney Committee, which received little attention in the report, is the notion that tolerance should be adjusted upward or downward when new information is received on risks or exposure. Tolerances of older compounds might be lowered to more clearly reflect tolerable residues rather than implementing a complete ban of these products. This procedure is used extensively by Canada and European countries. Using tolerances as maximum legal limits to which farmers, processors, and others adjust may be an efficient marginal procedure compared with complete pesticide switching when there are cancellations. Farmers can lower dosages used, limit late season use, or switch methods of application to prevent crop produce from being found above tolerances and confiscated or rejected by private or public inspectors. Allowing farmers to adjust pesticide residue management practices to reflect relative costs and benefits of pesticides will help reflect the spatial variation in pesticide benefits in the United States.

Finally, there must be more data on pesticide use and analysis of factors changing pesticide use. Information on use and benefits of use need to be related to pesticide residues by crop. The risk perceptions of consumers should not be considered in isolation from costs of pesticide use reduction.

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Summary

The EPA, in attempting to reconcile the oft times conflicting stipulations of FIFRA with the Delaney Clause of the FFDCA, has recently changed the method by which it will consider granting registrations to new pesticide products, or new uses to old pesticide products. This comes, not coincidentally, at a time when public concern has focused on the possible health risks involved in the use of chemical pesticides in modern agricultural production. Specifically, what level of cancer risk, if any, is acceptable in realizing the benefits of chemical intensive production in terms of high productivity, low consumer costs, and improved net farm revenue?

Under the FFDCA's Delaney Clause, residues of a known carcinogenic compound which will concentrate in a processed food cannot be granted a tolerance. Tolerances define the maximum levels of pesticide residues which may be legally present in foods and animal feed sold in interstate commerce. The FFDCA sets forth a strictly risk-based criterion when considering tolerances for food additives, while FIFRA stipulates taking into account the economic, social, and environmental costs and benefits of pesticide use. If a particular tolerance cannot win FFDCA approval, then no registration can be granted for use of the chemical on that food under FIFRA regardless of the possible benefits that particular use of the chemical would confer.

This report explores the Delaney Clause paradox and the EPA's rationale for altering the method by which pesticides are evaluated. An example of the economic effects of alternative levels of acceptable risk for food tolerances is provided as well as a critique of the methodology used by the National Academy of Sciences (NAS) in arriving at its recommendations. Our purpose is to clarify the implications of the rulemaking process underlying this issue of food safety. In 1985, NAS was provided an EPA grant to study EPA's methods for setting pesticide tolerance levels and to examine the current and likely effects of the Delaney Clause on the tolerance-setting process.

The NAS study indicated that strict application of the Delaney Clause would eliminate only about 20 percent of the estimated dietary oncogenic risk from consumption of pesticide residues in processed food. Another 35 percent of the risk would be eliminated from consumption of raw forms of the processed foods. However, the foods accounting for nearly one-half of the total estimated dietary risk are beyond the scope of the Delaney Clause, because under current EPA guidelines these foods have no processed form.

In addition, the system that has been used by EPA so far has the added undesirable feature of placing new pesticides that are barred from registration because of the strict reading of the Delaney Clause at a disadvantage relative to old products that are shown by new data to pose comparable or higher risks. Given the high costs of data development, there is little incentive to develop a new food use pesticide that shows carcinogenic potential, even if the risk it would pose would be minimal, and even if it could replace an old product that poses a higher risk, if initial registration is likely to be barred by the Delaney Clause. Thus, the development of new, lower risk pesticides to replace old, higher risk pesticides may have been retarded by the EPA's past implementation of the Delaney Clause.

There is at least "limited evidence" of carcinogenicity (virtually all from animal studies) for 66 or more of the approximately 350 food-use pesticides already approved for use. EPA expects this number to become somewhat larger as it receives and evaluates more studies on the food-use pesticides.

Under EPA's new policy, the agency would apply a uniform set of criteria to all FIFRA registration, tolerance, and food additive regulation decisions. If the residues of a pesticide on a particular food would pose no carcinogenic risk or only a negligible risk (that is 1×10^{-6})

over a 70-year life span, the pesticide's use on that food would be approved under both acts without any particular scrutiny of benefits (provided they meet the other requirements of FIFRA and the FFDCA).

The EPA's new interpretation of the Delaney Clause could have considerable economic implications for growers and consumers. By shifting from zero tolerance for carcinogenic pesticides under Delaney to negligible risk, many new pesticide products would potentially be able to be registered and subsequently marketed. At the same time, older product registrations not able to meet the negligible-risk standard would be cancelled. The new interpretation also could allow more of the "old" materials to remain.

To illustrate the economic implications of allowing some of the old materials to remain, the benefits of the negligible-risk standard are illustrated by assessing the short-term economic impacts on producer returns and consumer cost of banning use of two fungicides, chlorothalonil and the EBDC's, on fresh market tomatoes. The assessment assumes that current registered uses of these two fungicides would be continued on fresh market tomatoes under the new standard, but would not have been reregistered under the zero-risk standard.

Chlorothalonil is the singularly most extensively used oncogenic fungicide on fresh market tomatoes, with 75,000 treated acres or about 58 percent of the total 129,000 planted acres in the United States. The EBDC's, as a group, represent both extensively and intensively used suspected oncogenic fungicides on fresh market tomatoes with an estimated 74,000 treated acres.

Assuming yield losses and using a price elasticity of demand of -0.67 in the base case, a chlorothalonil ban would increase fresh market tomato prices by 9 percent from a 1984-88 average of $25.45 per cwt to $27.66 per cwt. An EBDC ban would result in an estimated price increase of 13 percent, and a ban on both chlorothalonil and the EBDC's would increase prices by 21 percent.

The assumed yield losses and associated higher prices of a chlorothalonil ban would increase revenues to growers by an estimated $8-$41 million. An EBDC ban would effect grower revenues, ranging from an decrease in revenue of $18 million to an increase of $27 million. The impact of banning both chlorothalonil and the EBDC's on grower revenues would range from a decrease of $17 million to an increase of $34 million.

For consumers, a ban on chlorothalonil or the EBDC's would increase the cost of fresh market tomatoes by about $34-$130 million. Banning both chlorothalonil and the EBDC's would result in increased costs of $79-$202 million to all consumers in the short term, both domestic and foreign. Domestic consumers would incur cost increases of $76-196 million.

The illustrated impacts reflect bans on registered uses of only one crop. Chlorothalonil and the EBDC's, however, are widely used fungicides with major uses in many fruit, vegetable, and specialty crops. Thus, the implications of the *de minimis* standard are that economic losses would be significantly reduced if:

1. the new standard allows either EBDC's or chlorothalonil to remain on the market, while both would have been banned under the previous standard (that is if *de minimis* allows more alternatives to remain on the market), or

2. the new standard allows new alternatives of comparable or better cost-effectiveness to EBDC's or chlorothalonil, but with less risk, to be registered, while the previous standard did not.

The economic and risk consequences assume the underlying correctness of the methods and data used to derive recommendations. The NAS study which caused EPA to alter its regulatory approach, however, had admitted limitations. Total change in oncogenic risk is likely to be underestimated for two reasons related to pesticide use. First, total risk was based on 28 of the 53 suspected oncogenic pesticides because of lack of tests to obtain Q* for the other 25 compounds. Second, there may be some inert materials in pesticide compounds which are also oncogenic which were not included. However, some of the major metabolites which are oncogenic were included, and the 28 compounds which were included constitute some of the most widely used pesticides.

There are also important reasons to believe that the use levels of the 28 included pesticides are overestimated. In the absence of complete use data, it was assumed that residues of all 28 pesticides equaled tolerance levels, which in turn implies that all 28 pesticides were used on every acre of every crop for which they were registered. Many of the pesticides are substitutes for one another. If one fungicide were used, another one would not also be used in many cases. More importantly, many of the 28 pesticides are older pesticides and have many registered uses for which they are no longer used, or used only on a small part of the crop area.

There are also identifiable biases in the assumed residue levels of each pesticide per unit of food. Because of lack of actual food residue data, the Delaney Committee assumed that all food had the legal maximum residues of each pesticide or the tolerance levels. This could lead to some underestimates because EPA does not currently recognize all possible livestock feeds and establish tolerances for them.

There are also major overestimates of all exposure levels by using 95-percent confidence interval food weights, ignoring food substitutions, and assuming that all food has the same contamination levels regardless of where residues are usually found. Also, most individuals substitute one form of a food for another, whereas the risk assessment assumed consumption of each form of the food. Overall, it is likely that food exposure (food consumption times residue concentration) is much lower than tolerance levels on all foods. Also, there is a tendency for foods with many pesticide tolerances to have high ranking as sources for oncogenic pesticides. This is largely related to number of tolerances or pesticides used on a particular crop, not amounts of pesticides used per unit of food consumed. Crops with large acreage and higher pest damage tend to have more registered pesticides than do minor use crops. The focus of the Delaney Committee on tolerances undoubtedly biased risk estimates toward a few major crops or food types. Taken together, these concerns argue against using the NAS study results as guidelines in targeting specific pesticide products or product groups for regulatory action. Rather, the study results suggest that more data collection on pesticide use and factors that change use patterns is necessary to effectively determine if pesticide residues on specific crops constitute rational health concerns.

The baseline lifetime risk of cancer among U.S. citizens is about 0.25, or one in four. The incremental risk from the 28 pesticides taken together was estimated to be 0.0058. Therefore, this "worst case" estimate showed pesticides on food are associated with less than 3 percent of all cancers.

EPA has the difficult task of reconciling the conflicting stipulations of FIFRA and the FFDCA concerning pesticide registration into a workable program that does not handicap the farmer nor jeopardize the health of the consumer. Though the EPA has recently adopted this modified negligible-risk approach in determining pesticide registration potential, some consumer and environmental groups have announced their intention to challenge the decision in the courts. The issue is not settled and may not be for some time.

Our purpose in compiling this report was to clarify the rulemaking process underlying the issue of food safety, provide an example of the economic consequences of banning single or groups of

pesticides for specific food group uses, and explain caveats in the original research which led to EPA's revamped approach to the pesticide registration process. The law relating to registration and tolerance levels is textually complex and formidable to those not familiar with its stipulations. The importance of recent changes in the law's interpretation to both consumers and growers requires affected individuals to become better informed about the causes and possible impacts of those changes.

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